MINUTES OF 336TH MEETING OF REGISTRATION BOARD HELD ON 4TH TO 6TH JUNE, 2024

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DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX.
PARK ROAD, CHAK SHEHZAD
ISLAMABAD.

336th meeting of Registration Board was held on 4th to 6th June, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex, Park Road, Islamabad.

The meeting was chaired by Dr. Muhammad Fakhruddin Aamir, Chairman,Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

Following members attended the meeting:

1.	Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, (HI-M, SI-M), Former Surgeon General Pakistan, Rawalpindi (On line)	Co-opted Member
2.	Mr. Muhammad Arif Ch, Director, Division of BE&R	Member
3.	Mr. Ajmal Sohail Asif, Director, Division of QA&LT	Member
4.	Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
5.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law &Justice, Islamabad.	Member
6.	Mr. Ghulam Mujtaba, Deputy Director, Rep. of IPO,Islamabad. (Online)	Member
7.	Mr. Imranullah Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
8.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o NFS, Islamabad	Member
9.	Mr. M. Ali Tasleem, Deputy Drugs Controller, DTL, Govt. of Punjab	Member
10.	Mirza Mehmood Baig, Director, DTL, Govt. of Baluchistan Quetta	Member
11.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore (Online)	Co-opted Member
12.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member
13.	Mr. Shahrukh Ali, Assistant Director, Rep. of Director,MD&MC Division	Member

Mr. Nadeem Alamgir & Mr. Saqib Zia (Pharma Bureau), Mr. Jalal-ud-Din Zafar (PPMA) and Mr. Amir Ilyas & Mr. Zia ul Haq (PCDA) attended the meeting as observers.

Item No. I. Confirmation of Minutes of 335th meeting of Registration Board

335th meeting of Registration Board was held on 25th April, 2024. Accordingly, draft minutes of the 335th meeting of Registration Board were prepared and circulated among the members through email on 15th May, 2024 for their perusal / approval / comments (if any). As per directions of Chairman Registration, Board members were requested to comment on the agenda item of veterinary products by 17th May, 2024 (09:00 am). While comments on rest of agenda were desired by 20th May, 2024 (09:00 am). Lt. Gen. Karamat A. Karamat (R) through email dated 17th May, 2023 commented *as "Biological portion recommended for approval."* Rest of the members did not comment. Hence minutes of 335th meeting of RB stand approved.

Decision: Registration Board noted the information and unanimously confirmed minutes of 335th meeting of Registration Board.

Item No. I Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
2.	Dr. M. Haseeb Tariq	Evaluator PEC-III
3.	Mst. Farzana Raja	Evaluator PEC-IV
4.	Mst. Iqra Aftab	Evaluator PEC-V
5.	Dr. Farhadullah	Evaluator PEC-XI
6.	Mr. Shahid Nawaz	Evaluator PEC-XIII
7.	Ms. Saima Hussain	Evaluator PEC-XV
8.	Ms. Sana Kanwal	Evaluator PEC-XX
9.	Mr. M. Tahir Waqas	Evaluator PEC-XXI
10.	Ms. Maham Misbah	Evaluator PEC-XXIII
11.	Mr. Hafiz Asif Iqbal	Evaluator PEC-XXIV
12.	Ms. Najia Saleem	Evaluator PEC-XXV
13.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
14.	Mr. Salateen Waseem Philip	Deputy Director (PEC)
15.	Mr. Sarfraz	Assistant Director (PE&R)
16.	Mr. Adil Saeed	Deputy Director (PE&R)

Agenda of Evaluator PEC-II

Case no. 01 Registration applications for local manufacturing of (Human) drugs on Form 5F

a. New cases

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seatle Pvt Ltd. 45 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 33020 dated 17-11-2022
	Details of fee submitted	Rs.75,000/- dated 12-10-2022
	The proposed proprietary name / brand name	**Tamdow-S 6/0.4 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vesomni Tablet by M/s Astellas Pharma Ltd., EMA Approved.
	For generic drugs (me-too status)	Tamsolin -S by M/s Getz Pharma
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 04- 01-2022.
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt. Ltd Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Solifenacin Succinate & Tamsulosin HCl is not present in Pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Tamsulosin HCL Batches: (8000173-039(A), 8000173-045(A), 8000173-046(A)) Solifenacin Succinate Batches: (8000173-039(B), 8000173-045(B), 8000173-046(B))
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence and CDP Studies data in three dissolution mediums of pH 1.2, 4.5 & 6.8 has been submitted against the Tamsolin-S tablet pf M/s Getz Pharma
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd. Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
API Lot No.	Tamsulosin HCl: AT0018-002 Solifenacin Succinate: AT0019-003
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21L133	21M294	--
Batch Size	110,000 tab	110,000 tab	--
Manufacturing Date	11-2021	12-2021	--
Date of Initiation	29-12-2021	20-01-2022	--
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator(Ammar):

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosin HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	

3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	
	• Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	

Decision: Deferred for submission of reply to above cited shortcomings

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 04-01-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of section dated 13-06-2017 specifying Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 30453 dated 27-10-2022
	Details of fee submitted	Rs.75,000/- dated 24-10-2022

	The proposed proprietary name / brand name	**Soglu-Met XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……. ….10mg Metformin HCl (as extended release)…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Pharmaceutical form of applied drug	Extended Release Tablet
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	Pack Size: 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab 25/1000mg of M/s Hilton Pharma Pvt Ltd
	Name and address of API manufacturer.	**EMPAGLIFLOZIN :** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd. **Address:** Fluoride industrial park, Fuxin city, Liaoning province, 123000, China. **METFORMIN HCl:** **Name:** AARTI DRUGS LIMITED **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV

		conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Reference product Empagen-M XR 10/1000mg Tablets manufactured by Ferozsons Laboratories Limited. Firm has submitted CDP results of their product against the reference product Empagen-M XR 10/1000mg Tablets in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	E-20190920-D02-E06-01 MEF/10030953	
Description of Pack (Container closure system)	HDPE Bottles	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST21J025	ST21J026
Batch Size	5000 Tablet	5000 Tablet
Manufacturing Date	09-2021	09-2021
No. of Batches	02	

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 04-01-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of section dated 13-06-2017 specifying Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 30454 dated 27-10-2022
	Details of fee submitted	Rs.75,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**Soglu-Met XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……. ….25mg Metformin HCl (as extended release)…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Pharmaceutical form of applied drug	Extended Release Tablet
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	Pack Size: 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab 25/1000mg of M/s Hilton Pharma Pvt Ltd
	Name and address of API manufacturer.	**EMPAGLIFLOZIN :** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd. **Address:** Fluoride industrial park, Fuxin city, Liaoning province, 123000, China. **METFORMIN HCl:** **Name:** AARTI DRUGS LIMITED **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Reference product Empagen-M XR 25/1000mg Tablets manufactured by Ferozsons Laboratories Limited. Firm has submitted CDP results of their product against the reference product Empagen-M XR 25/1000mg Tablets in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	E-20190920-D02-E06-01 MEF/10030953	
Description of Pack (Container closure system)	HDPE Bottles	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST21J029	ST21J030
Batch Size	5000 Tablet	5000 Tablet
Manufacturing Date	09-2021	09-2021
No. of Batches	02	

	Name, address of Applicant / Marketing	**M/s Global Pharmaceuticals (Pvt) Ltd**

4.	**Authorization Holder**	**Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 04-01-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of section dated 13-06-2017 specifying Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 30764 dated 31-10-2022
	Details of fee submitted	Rs.30,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**Soglu-Met XR 5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……. ….5mg Metformin HCl (as extended release)…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Pharmaceutical form of applied drug	Extended Release Tablet
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	Pack Size: 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab 5/1000mg of M/s Hilton Pharma Pvt Ltd
	Name and address of API manufacturer.	**EMPAGLIFLOZIN :** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd. **Address:** Fluoride industrial park, Fuxin city, Liaoning province, 123000, China. **METFORMIN HCl:** **Name:** AARTI DRUGS LIMITED **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Reference product Empagen-M XR 5/1000mg Tablets manufactured by Ferozsons Laboratories Limited. Firm has submitted CDP results of their product against the reference product Empagen-M XR 5/1000mg Tablets in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	E-20190920-D02-E06-01 MEF/10030953
Description of Pack (Container closure system)	HDPE Bottles
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST21J023	ST21J024
Batch Size	5000 Tablet	5000 Tablet
Manufacturing Date	09-2021	09-2021
No. of Batches	02	

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 32004 dated 07-11-2022
	Details of fee submitted	Rs.30,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**Soglu-Met XR 12.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……. 12.5mg Metformin HCl (as extended release)…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP Certificate dated 04-01-2022 based on inspection conducted on 03-01-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of section dated 13-06-2017 specifying Tablet (General) Section
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved.
For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab 5/1000mg of M/s Hilton Pharma Pvt Ltd
Name and address of API manufacturer.	**Empagliflozin :** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd.

	Address: Fluoride industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** **Name:** AARTI DRUGS LIMITED **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Reference product Empagen-M XR 12.5/1000mg Tablets manufactured by Ferozsons Laboratories Limited. Firm has submitted CDP results of their product against the reference product Empagen-M XR 12.5/1000mg Tablets in 3 dissolution medias.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	E-20190920-D02-E06-01 MEF/10030953		
Description of Pack (Container closure system)	HDPE Bottles		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST21J027	ST21J028	--
Batch Size	5000 Tablet	5000 Tablet	--
Manufacturing Date	09-2021	09-2021	--
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Promig Plus 375mg/20mg Tablet and Promig Plus 375mg/20mg Tablet, for which the inspection was conducted on 14-03-2019 and the report was presented in 289th meeting of Registration Board. The report confirms following points:

	• The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML issued by NMPA of China. **Metformin HCl:** Firm has submitted copy of GMP Certificate (23064344) dated 15-03-2023 issued by Food And Drug Control Administration India.
Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared on 10-01-2020 specifying 1.5Kg of Empagliflozin. The invoice is cleared by AD (I&E) DRAP, with Invoice No HN19120501-H. **Metformin HCl:** Firm has submitted copy of License to import issued on 05-08-2020 specifying 1000KG of Metformin HCl. The invoice is cleared by AD (I&E) DRAP, with Invoice No EXP/302/20-21.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Firm has referred to the drug substance eanalytuical procedure submitted by m/s global Pharma wherein solubility of Empagliflozin ha sbeen declared as "Very slightly soluble".
3.	**3.2.S.4.2**	Drug substance analytical procedure of Metformin HCl is not as per the latest monograph of USP for Metformin HCl.	Revised analytical method submitted.
4.	**3.2.S.4.3**	Analytical method verification studies shall be submitted from M/s Global Pharmaceuticals for Metformin HCl for the analytical method as per latest monograph of USP.	Submitted.
7.	**3.2.P.3.5**	Submitted process validation protocol does not include details of in-process test by way of Assay at the drug layering stage, applied to confirm that desired content for Empagliflozin has been achieved via active coating.	We will revise the protocol and will follow the same for validation of 1st three commercial batches after registration.
9.	**3.2.P.8.3**	• As per submitted analytical record the Assay & Dissolution analysis has been	Assay & Dissolution analysis has been performed on

			performed at different wavelength than that specified in the submitted drug product analytical procedure. • Justification shall be submitted on basis of performance based evidence for adding 5% overage of "Empagliflozin" in the applied batch formulation. • Evidence of availability of facility of HDPE packaging of tablets.	wavelength specified in submitted drug product analytical control procedure i.e. 261nm for Metformin HCI and 210nm for Empagliflozin. We have performed analysis / acquisition on Hitachi HPLC at said dual wavelengths but system generates the report on single auto maximum average wavelength that display on the chromatogram i.e. 225nm and has no link with mentioned areas. All the area mentioned is of those dual wavelengths. System generated instrument method report is submitted. Additon of 5% overage of "Empagliflozin" in the applied batch formulation was done to compensate the coating loss during active coating.

Decision: Registration Board approved the applications of Soglu-Met XR 10/1000 mg Tablet, Soglu-Met XR 25/1000 mg Tablet, Soglu-Met XR 5/1000mg Tablet & Soglu-Met XR 12.5/1000mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30433 dated 27-10-2022
	Details of fee submitted	Rs.75,000/- dated 18-10-2022
	The proposed proprietary name / brand name	**OEM Co-Pack Oral Rehydration Salts+zinkup 20mg Oral Dispersible Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Sodium Chloride…1.3gm Potassium Chloride…0.75gm Sodium Citrate…1.45gm Glucose…6.75gm Each Oral Dispersible Tablet Contains: Zinc Sulphate Monohydrate 54.9mg Eq. to Elemental Zinc…20mg
	Pharmacotherapeutic Group of (API)	**OEM Sachet:**

		BP Specifications. **Zinkup 20mg Oral Dispersible Tablet:** USP specifications.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Recommende din WHO EML
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.4**	➢ Latest GMP inspection report of the drug product manufacturer, conducted within last three years shall be submitted,	
3.	**1.6.5**	➢ Valid GMP certificates of drug substance manufacturers shall be submitted.	
4.	**3.2.S.3**	Details shall be submitted as per CTD guidance document for all Drug substances of ORS Sachet.	
5.	**3.2.S.4**	Detailed analytical procedures and specifications for the testing of drug substance shall be provided from Drug substance manufacturer for all Drug substances of ORS Sachet.	
7	**3.2.S.4.4**	➢ COA of drug substance from the drug substance manufacturer shall be submitted for all Drug substances of ORS Sachet.	
8.	**3.2.S.7.3**	Stability studies data as per Zone IV conditions shall be submitted for all Drug substances of ORS Sachet.	
9.	**3.2.S.4.1 (Zinc Sulphate)**	Details of drug substance specifications and analytical procedure shall be submitted form drug substance manufacturer.	
10.	**3.2.S.4.2 (Zinc Sulphate)**	Submitted Assay method for Zinc sulphate is different form that recommended by USP monograph.	
11.	**3.2.S.4.3 (Zinc Sulphate)**	Analytical method verification studies for Assay analysis of Zinc suilphate shall be submitted as per the method recommended in USP monograph.	
12.	**3.2.S.5 (Zinc Sulphate)**	As per USP monograph reference standard of Zinc sulphate is required for Assay analysis, while frim has not submitted any such document.	
13.	**3.2.S.7.3 (Zinc Sulphate)**	Stability studies data of three batches shall be submitted as per Zone IV conditions with testing as per USP monograph.	
14.	**3.2.P.5.2**	Analytical method for the Assay of Potassium and Soidum in ORS sachet is not as per BP monograph.	
15.	**3.2.P.5.3**	Analytical method verification studies for ORS sachet shall be submitted as per BP monograph.	

Decision: Deferred for submission of reply to the above cited shortcomings.

7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma. 23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Venus Pharma. 23 km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 27913 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- dated 31-05-2022
	The proposed proprietary name / brand name	**Cynaocobalamin 1cc injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Cyanocobalamin…500mcg
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Not verified
	For generic drugs (me-too status)	--
	Proposed Pack size	As per SRO

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.4**	➢ Submit evidence of validity of DML of the drug product manufacturer. ➢ Latest GMP inspection report of the drug product manufacturer, conducted within last three years shall be submitted,	
2.	**1.5.9**	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
3.	**1.6.5**	➢ Name of the drug substance manufacturer declared on submitted GMP certificate is different from that mentioned in section 1.6.5.	
4.	**3.2.S.4.1**	➢ Justification shall be submitted for not including following tests, as recommended by BP monograph, in the drug substance specifications submitted by M/s Venus pharma: i. Identification test by Chromatography. ii. Related substances test.	
5.	**3.2.S.4.2**	Detailed analytical procedures for the testing of drug substance shall be provided.	
6.	**3.2.S.4.3**	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
7	**3.2.S.4.4**	Justification shall be submitted for not performing following tests in batch analysis of drug substance by M/s Venus pharma: ➢ Identification test by Chromatography. ➢ Related substances test. ➢ Microbial tests.	
8.	**3.2.S.7.3**	Long term stability studies does not include performance of identification test.	

Decision: Deferred for submission of reply to the above cited shortcomings.

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.**
	Name, address of Manufacturing site.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificatebased on inspection conducted on 13-07-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of DML dated 11-04-2018 specifying Liquid Injectable Vial (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 30450 dated 27-10-2022
	Details of fee submitted	Rs.30,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Liziliv 600mg/300ml Infusuion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Linezolid…….2mg
	Pharmacotherapeutic Group of (API)	**Synthetic**
	Pharmaceutical form of applied drug	Extended Release Tablet
	Reference to Finished product specifications	Innovator's Specs
Remarks of Evaluator: • Module II and Module 3.2.S shall be re submitted in sequential order of Form 5F in-line with the "Guidance document for submission of application on form 5-F (CTD) for registration of pharmaceutical drug products for human use" available on official website of DRAP www.dra.gov.pk.		
Decision: Deferred for submission of reply to the above cited shortcomings.		
9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 33448 dated 21-11-2022
	Details of fee submitted	Rs.75,000/- dated 31-10-2022
	The proposed proprietary name / brand name	**Exempa-Lin Met 12.5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Linagliptin…2.5mg Metformin HCl as Extended Release…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**

	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 33445 dated 21-11-2022
	Details of fee submitted	Rs.75,000/- dated 31-10-2022
	The proposed proprietary name / brand name	**Exempa-Lin Met 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Linagliptin…2.5mg Metformin HCl as Extended Release…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 33445 dated 21-11-2022
	Details of fee submitted	Rs.75,000/- dated 31-10-2022
	The proposed proprietary name / brand name	**Exempa-Lin Met 25/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg Metformin HCl as Extended Release…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 33446 dated 21-11-2022
	Details of fee submitted	Rs.75,000/- dated 31-10-2022
	The proposed proprietary name / brand name	**Exempa-Lin Met 10/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…5mg Metformin HCl as Extended Release…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.S.1.3	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Empagliflozin is slightly soluble in water as per literature from USFDA and EMA, there was an error in DMF from drug substance manufacturer.
3.2.P.1	• Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. • Justification shall be submitted for proposed quantity of Arginine in the formulation. • Justification shall be submitted on basis of performance based evidence for adding 20% overage of "Empagliflozin" & "Linagliptin" in the applied batch formulation. • Justification shall be submitted for not including Arginine in the applied formulation as used by the innovator drug product. • Clarification shall be submitted for the excipient used for the extended release profile of Metformin HCl core.	• Seal coat is applied to metformin core to avoid contact of IR layer of Empagliflozin and Linagliptin. If no seal coat is applied then the drug will bound to extended release matrix of metformin and will retard the release profile of IR layer. • Since the drugs are applied in the IR layer via coating process, so process loss is mandatory because of coating exhaust air. It is kept at optimum of 20% overage, but in commercial batches we will further optimize it to reduce the overage percentage. • We have manufactured our trials without arginine and our formulation is stable because each drug coat is

		separated via a seal coat which is avoiding direct contact of drug from each other, same has been observed in Real time /Accelerated stability studies. • For extended release profile HPMC 4000grade is used and final release profile is comparable with that of innovator. CDP results have been attached.
3.2.P.3.5	➢ Submitted Process validation protocol shall include test of Dissolution at the compression stage of Metformin HCl core tablet as in-process test.	Updated Process validation protocol including test of Dissolution at the compression stage of Metformin HCI core tablet as in-process test (page no:14) is **attached** for your reference.
3.2.P.5.1	➢ Submitted specifications declared as "In house specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC ➢ Justification shall be submitted for variation in the sampling time points for dissolution test of Metformin HCl from that recommended by the innovator drug product literature approved by US FDA.	CDP of Metformin HCL has been done as per recommended by the drug product literature by USFDA while dissolution test in stability reports has been performed as per USP.

Decision: Registration Board approved the applications of Exempa-Lin Met 12.5/2.5/1000 mg Tablet, Exempa-Lin Met 5/2.5/1000 mg Tablet, Exempa-Lin Met 25/5/1000 mg Tablet & Exempa-Lin Met 10/5/1000 mg Tablet

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

13.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34692 dated 30-11-2022
	Details of fee submitted	Rs.75,000/- dated 15-11-2022
	The proposed proprietary name / brand name	**Elagol 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium Eq. to Elagolix ……. 200mg

	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis
	Reference to Finished product specifications	As per Helix Pharma standard
14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1177 dated 13-01-2023
	Details of fee submitted	Rs.75,000/- dated 15-11-2022
	The proposed proprietary name / brand name	**Elagol 150mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium Eq. to Elagolix …… 150mg
	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis
	Reference to Finished product specifications	As per Helix Pharma standard

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	➢ Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl shall be submitted.	Submitted
2.	**3.2.S.4**	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from M/s Helix Pharma.	Submitted
3.	**3.2.S.5**	COA of reference/working standard used for the analysis of drug substance by M./s Helix Pharma, shall be submitted.	Submitted
4.	**3.2.P.2.2.1**	Details of the innovator product against which CDP & PE studies are performed i.e. name of manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted with pictorial evidence.	Firm has submitted details of Orilissa tablet of M/s AbbVie Inc.
5.	**3.2.P.5.1**	• Submitted specifications declared as "In house specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC	
6.	**3.2.P.8.3**	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP shall be submitted.	• Firm has submitted copy of commercial invoice attested y AD I&E DRAP, Karachi dated 30-11-2020 for import of 1.645 Kg of Elagolix sodium.

		➢ Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• Audit trail report submitted.

Decision: Registration Board approved the applications of Elagol 200mg Tablet & Elagol 150mg Tablet with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for each strength correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 32467 dated 11-11-2022
	Details of fee submitted	Rs.30,000/- dated 05-10-2022
	The proposed proprietary name / brand name	**Empaglif-M 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. …. 5mg Metformin HCl…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
	1.3.4	➢ Latest GMP inspection report of the drug product manufacturer, conducted within last three years shall be submitted,	
1.	**1.6.5**	➢ Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl shall be submitted.	
2.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	
3.	**3.2.S.4**	➢ Submit drug substance analytical procedure of Empagliflozin form drug substance manufacturer. ➢ Justification shall be submitted for declaring specifications of Metformin HCl as " In-House" in section 3.2.S.4.1	

	5.	**3.2.P.2.2.1**	➢ Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product	
	6.	**3.2.P.3.2**	Innovator drug product literature states as under: "To combine the low amount of Empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing Empagliflozin was chosen." • In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozin with binder solution. Justification shall be submitted in this regard.	
	7.	**3.2.P.5.2**	• Justification shall besubmitted for adopting UV Spectrophotometric method for Assay test of Metformin HCl in drug product. • Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Analytical method validation studies for the Dissolution method shall be submitted, particularly specificity parameter for Metformin HCl analpysis, performed on UV spectrophotometer.	

Decision: Deferred for submission of reply to the above cited shortcomings.

16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd.** **44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34285 dated 28-11-2022
	Details of fee submitted	Rs.30,000/- dated 10-11-2022
	The proposed proprietary name / brand name	**Emlit 10/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…….5mg
	Pharmacotherapeutic Group of (API)	**Linaglitpin:** Inhibitor of DPP-4, **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd.** **44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd.

		44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34285 dated 28-11-2022
	Details of fee submitted	Rs.30,000/- dated 10-11-2022
	The proposed proprietary name / brand name	**Emlit 25/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin……5mg
	Pharmacotherapeutic Group of (API)	**Linaglitpin:** Inhibitor of DPP-4, **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
2	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "insoluble". Justification shall be submitted in this regard.	Supplier stated that "Empagliflozin has a certain degree of hydrophobicity, and ils & solubility in water and buffer solution is relatively small. During the dissolution process. particle aggregation is prone to which further prolong the dissolution occur, time of the sample, redhuce solubility and cause the detection results to fluctuate at the edge of the limit. Therefore, the limit was slightly relaxed at that time. Later, during the testing process, we paid attention to removing agglomerated particles from the samples, ensuring that the solubility limit of the sample in water was consistent with the innovator drug product literature.
3.	**3.2.S.4**	➢ Analytical method verification studies of drug substances shall be submitted from M/s Genix Pharmaceuticals	Submitted

Decision: Registration Board approved the applications of Emlit 10/5 mg Tablet & Emlit 25/5 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 35344 dated 06-12-2022
	Details of fee submitted	Rs.30,000/- dated 02-12-2022
	The proposed proprietary name / brand name	**Cyclozon 5ml Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Opthalmic Emulsion Contains: Ciclosporin …… 0.5mg
	Pharmacotherapeutic Group of (API)	Steroid-Sparing Immunosuppressant ATC Code: L04AD01
	Reference to Finished product specifications	BP

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3**	➢ Submit evidence of approval of required manufacturing facility of "Eye/Ear solution" section from Licensing Division.	Firm has submitted copy of letter for grant of additional section including Ear/Eye Drops –II (General) section issued by Secretary CLB dated 25-10-2023
2.	**1.5.6**	➢ Submit evidence of availability of USP monograph for applied formulation as Finished drug product specifications have been claimed as per USP,	We have followed BP monograph for product testing , there was the typographical mistake.
3.	**2.3.R**	➢ Submitted batch manufacturing record does not include details of the sterilisation process.	Submitted
4.	**3.2.P.1**	➢ Clarification shall be submitted regarding the maintenance of sterility of multi dose formulation since applied formulation does not contain any preservative.	We used specifalized botlle in which protective cap an dpullcove ris used as per innovator. Horizon already use this type of bottle in our product Tobrazon-D eye drops.
5.	**3.2.P.3.3**	➢ Submitted manufacturing process flow does not include any details for the sterility of applied formulation.	Submitted
6.	**3.2.P.3.4**	➢ Sterilisation has not been identified as Critical step in the manufacturing procedure.	Submitted
7.	**3.2.P.5.1**	➢ Submitted drug product specifications have been referred to BP monograph while section 1.5.6 declare it as per USP.	We have followed BP monograph for product testing , there was the typographical mistake.
8.	**3.2.P.7**	➢ Details of the material of construction of the container closure system shall be submitted.	LDPE bottle has been used.
9.	**3.2.P.8.3**	➢ Details of the available stability chambers shall be submitted. ➢ Justification shall be submitted for submitting stability studies data of two batches only.	• Firm has submitted copy of License to import issued by AD I&E DRAP dated 10-05-2022 for Cyclosporine 5gm.

			➢ Commercial invoice for the drug import shall be submitted.	• Firm has referred to CTD guidance document for selection of batch sizes. • Details of stability chamber submitted.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37587 dated 23-12-2022
	Details of fee submitted	Rs.30,000/- dated 20-01-2023
	The proposed proprietary name / brand name	**Emjure-L 5/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin.…25mg Linagliptin……5mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37586 dated 23-12-2022
	Details of fee submitted	Rs.30,000/- dated 20-01-2023
	The proposed proprietary name / brand name	**Emjure-L 5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin.…10mg Linagliptin……5mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics

		ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	➢ Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl shall be submitted.	Submitted
2.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Firm has submitted revised section of DMF
3.	**3.2.S.1.3**	➢ Clarification shall be submitted regarding the isomeric form of the drug substance.	Submitted
4.	**3.2.S.4**	➢ Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications.	Firm has submitted drug substance specifications from drug substance manufcaturer
5.	**3.2.S.4.4**	➢ Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard.	Firm has submitted COA from drug substance manufacturer declaring test of Enantiomeric purity
6.	**3.2.P.5.2**	• Reference shall be submitted for the dissolution parameters adopted for the drug product dissolution test.	Submitted
7.	**3.2.P.8.3**	• Firm has submitted copy of clearance certificates issued by AD I&E DRAP, Peshawar, in name of M/s Weatherfolds Pharmaceuticals, Hattar Pakistan. Justification shall be submitted in this regard	We have loan the material from M/S Weather folds Pharmaceuticals, Hattar Pakistan. The loan letter has been submitted

Decision: Registration Board approved the applications of Emjure-L 5/25 mg Tablet & Emjure-L 5/10 mg Tablet. The firm shall submit fee of Rs. 7,500/- for each strength for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals.** **Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate,

		Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No364 dated 04-01-2023
	Details of fee submitted	Rs.30,000/- dated 07-12-2022
	The proposed proprietary name / brand name	**Empazin M 5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin ……. 5mg Metformin HCl ……850mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals.** **Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 36120 dated 12-12-2022
	Details of fee submitted	Rs.30,000/- dated 01-12-2022
	The proposed proprietary name / brand name	**Empazin M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin ……. 12.5mg Metformin HCl ……500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals.** **Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 36119 dated 12-12-2022
	Details of fee submitted	Rs.30,000/- dated 01-12-2022
	The proposed proprietary name / brand name	**Empazin M 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin ……. 5mg Metformin HCl ……500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.**	➢ Latest GMP inspection report conducted within last three years, of the drug product manufacturer shall be submitted.	Firm has submitted copy of GMP inspection report conducted on 11-12-2020 recommending grant of cGMP certificate
3.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Firm has submitted revised section of the DMF form drug substance manufacturer declaring solubility as "very slightly soluble.
6.	**3.2.P.5.1**	The USFDA review documents of innovator product i.e., Synjardy declares the dissolution specifications as "NLT Q in 20 minutes", while you have applied dissolution limits of NLT Q in 30minutes. Justification shall be submitted in this regard.	Limit of NLT Q in 30 minutes is selected from the FDA dissolution list. However, the dissolution specifications of innovator's product "Synjardy" was also considered and followed. The dissolution of product was achieved to the limit of NLT 80% (Q) in less than 20 minutes. However as per FDA dissolution method database the limit of 30 minutes was selected.

Decision: Registration Board approved the applications of Empazin M 5/850 mg Tablet, Empazin M 12.5/500 mg Tablet & Empazin M 5/500 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

24.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**

	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37710 dated 26-12-2022
	Details of fee submitted	Rs.30,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Elzanor XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Empagliflozin……. …. 12.5mg Metformin HCl…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Tabros Specs
25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37711 dated 26-12-2022
	Details of fee submitted	Rs.30,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Elzanor XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Empagliflozin……. …. 10mg Metformin HCl…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Tabros Specs
26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37709 dated 26-12-2022
	Details of fee submitted	Rs.30,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Elzanor XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Empagliflozin……. …. 5mg Metformin HCl…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Tabros Specs
27.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37712 dated 26-12-2022
	Details of fee submitted	Rs.30,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Elzanor XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Empagliflozin……. …. 12.5mg Metformin HCl…...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Tabros Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
3.	**3.2.S.4.1**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	During the review of Empagliflozin, we have already noticed that the solubility does not comply with USFDA and EMA standards. We raised a query to the drug substance manufacturer dated March, 27 2024 regarding the solubility discrepancy. the manufacturer has acknowledged their mistake and provided a revised Certificate of Analysis (COA)

			to ensure compliance. Additionally, the manufacturer has provided a statement letter Drug substance COA from M.s tabros Pharma also declares the solubility in water as practically insoluble.
4.	**3.2.P.3.5**	➢ Justification shall be submitted for not considering "Dissolution test" for Metformin HCl as critical quality attribute at the compression stage of Metformin HCl extended release core tablet. ➢ Submitted process validation protocol does not include details of in-process test by way of Assay at the drug layering stage, applied to confirm that desired content for Empagliflozin has been achieved via active coating.	➢ We considered the dissolution test for Metformin HCl as a critical quality attribute during the compression stage and had already mentioned it in the Pharmaceutical development phase. However, it was mistakenly omitted from the process validation. We have now incorporated the dissolution test for Metformin HCI at the compression stage. The revised Process Validation protocol has been submitted. ➢ The process validation protocol has been revised to include in-process details specifically the assay of empagliflozin at the drug layering stage
5.	**3.2.P.5.1**	• Submitted specifications declared as "Tabros specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC	Firm has submitted revised drug product specifications referreing it as per innovator.
6.	**3.2.P.5.3**	• Justification shall be submitted that how the regarding the declaration of "stability indicating method" and "specificity" of the applied method without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component.	We have a limited number of HPLCs equipped with a photodiode array detector. Unfortunately, all validation was performed using only a UV detector. We acknowledge the comments of the competent authority and are providing all evidence, such as chromatograms, and have performed peak purity analysis using the diode array detector.

Decision: Registration Board approved the applications of Elzanor XR 12.5/1000 mg Tablet , Elzanor XR 5/1000 mg Tablet & Elzanor XR 25/1000 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1862 dated 19-01-2023
	Details of fee submitted	Rs.75,000/- dated 26-12-2022
	The proposed proprietary name / brand name	**ELM XR 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immediate release layer)…5mg Linagliptin (as Immediate release layer) …2.5mg Matformin Hcl (as extended release core)…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1861 dated 19-01-2023
	Details of fee submitted	Rs.75,000/- dated 26-12-2022
	The proposed proprietary name / brand name	**ELM XR 25/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immediate release layer)…25mg Linagliptin (as Immediate release layer) …5mg Matformin Hcl (as extended release core)…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1860 dated 19-01-2023
	Details of fee submitted	Rs.75,000/- dated 26-12-2022
	The proposed proprietary name / brand name	**ELM XR 10/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immediate release layer)…10mg Linagliptin (as Immediate release layer) …5mg Matformin Hcl (as extended release core)…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1863 dated 19-01-2023
	Details of fee submitted	Rs.75,000/- dated 26-12-2022
	The proposed proprietary name / brand name	**ELM XR 12.5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immediate release layer)…12.5mg Linagliptin (as Immediate release layer) …2.5mg Matformin Hcl (as extended release core)…1000mg
	Pharmacotherapeutic Group of (API)	**Linagliptin:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
Evaluation by PEC[II]:		

Sr.#	Section#	Observation	Firm's response
2.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Firm has submitted revised section of the DMF form drug substance manufacturer declaring solubility as "very slightly soluble.
3.	**3.2.P.3.5**	➢ Submitted Process validation protocol shall include test of Dissolution at the compression stage of Metformin HCl core tablet as in-process test.	Firm has submitted revised prodcess validation protocol.

Decision: Registration Board approved the applications of ELM XR 5/2.5/1000 mg Tablet, ELM XR 25/5/1000 mg Tablet, ELM XR 10/5/1000 mg Tablet & ELM XR 12.5/2.5/1000 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

32.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 2555 dated 26-01-2023
	Details of fee submitted	Rs.30,000/- dated 20-01-2023
	The proposed proprietary name / brand name	**Emjuremet 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. …. 12.5mg Metformin HCl…...500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	➢ Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl shall be submitted.	Submitted
2.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Firm has submitted revised section of DMF

3.	**3.2.S.4**	➢ Submit drug substance analytical procedure of Empagliflozin form drug substance manufacturer. ➢ Justification shall be submitted for declaring specifications of Metformin HCl as " In-House" in section 3.2.S.4.1	Submitted. The word "In house" in section 3.2.S.4.1 clause (b) was typographically written wrong. We have performed the metformin HCl drug substance as per B.P specifications so we have this section to B.P. specifications.
4.	**3.2.S.4.4**	➢ Manufacturing site declared on COA of Metformin HCl from drug substance manufacturer is different from that mentioned in section 1.6.5 & 3.2.S.2.1	Firm has submitted revised section 1.6.5 & 3.2.S.2.1
5.	**3.2.P.2.2.1**	➢ Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product	We have performed CDP and Pharmaceutical equivalence studies against competitor brand as per DRAP guidelines.
6.	**3.2.P.3.2**	Innovator drug product literature states as under: "To combine the low amount of Empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing Empagliflozin was chosen." • In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozin with binder solution. Justification shall be submitted in this regard.	In the CTD flow chart layout the dry granulation manufacturing method was written typographically wrong. We have adopted the wet granulation processing method to combine the low quantity of empagliflozin with high quantity of Metformin HCl. The filled batch manufacturing record has been attached as evidence.
7.	**3.2.P.5.3**	• Analytical method validation studies for the Dissolution method shall be submitted, particularly specificity parameter for the dual wavelength applied.	Submitted
8.	**3.2.P.8.3**	• Firm has submitted copy of clearance certificate issued by AD I&E DRAP, Peshawar, in name of M/s Weatherfolds Pharmaceuticals, Hattar Pakistan. Justification shall be submitted in this regard	We have loan the material from M/S Weather folds Pharmaceuticals, Hattar Pakistan. The loan letter has been submitted

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for each strength correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 12660 dated 24-05-2022
	Details of fee submitted	PKR 30,000/- Dated 24-05-2022
	The proposed proprietary name / brand name	**EMP-MET XR 5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains: Empagliflozin …… 5mg Metformin HCl (extended release) ……. 1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
34.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12663 dated 24-05-2022
	Details of fee submitted	Rs.30,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Emp-Met XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Empagliflozin…25mg Metformin HCl (extended release) …1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12662 dated 24-05-2022
	Details of fee submitted	Rs.30,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Emp-Met XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl (extended release) …1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12661 dated 24-05-2022
	Details of fee submitted	Rs.30,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Emp-Met XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Empagliflozin…10mg Metformin HCl (extended release) …1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs

Remarks of Evaluator:

Section no.	Observations	Firm's response
1.5.2	Submitted label claim shall be elaborated with respect to the release profile of Empagliflozin and Metformin HCl.	Firm has submitted elaborated label claim for extended release core of Metfromin HCl
1.6.5	Submit valid GMP certificate/DML of the drug substance manufacturer of Metformin HCl, issued by the relevant regulatory authority.	Firm has submitted GMP certificate issued by Food and Drugs Control Administration, Gujarat, India valid till 20-08-2025.
2.3.R.1.1	• As per innovator drug product literature, a layer film coating is established between the Metformin HCl core and Active coating of Empagliflozin active coating layer. • The submitted product development record does not reflect performance of dissolution for Metformin HCl before proceeding for seal & active coating step. Justification shall be submitted for proceeding further without establishing the Dissolution profile of Metformin HCl. • The submitted product development record does not reflect performance of Uniformity of dosage units test by way of Assay for Empagliflozin before proceeding for final film coating step. Justification shall be submitted for proceeding further without establishing the content of Empagliflozin. • Submitted BMR declare dispensing of Empagliflozin as per 100% content of desired label claim. Justification shall be submitted that how dispensed quantity will produce 100% content of Empagliflozin, when it is being included by way of Active coating and how the wastage of coating solution will be compensated.	A seal coat or barrier coating is applied over the tablet core to protect against water penetration into the tablet from the active coatings to follow. When we go through the literature review, we found barrier coating was mentioned optional in World Intellectual Property Organization/Patent Cooperation Treaty (WIPO/PCT) patent WO2017093419 A1 and in our developed product Metformin HCI core doesn't show any interaction with active coating 2. In response to query # 2.3.R.1.1, it is stated that all the parameters which lead to the wastage of solution were closely monitored by increasing the distance of gun from the core bed. 2. Decreasing the spray speed of the gun and proper atomization of the gun, so that its mist doesn't touch the base and sides of the pan resulting in wastage of the solution. 3. By optimizing the temperature. Suction pressure of the exhaust pump was kept low so that solution may not be exhausted out before it touches the bed. Moreover, the tablet loss for the in process testing was almost 6-8% of the total trial size (1500 tablets) before it reaches to the stage of active coating. Whereas active coating solution of

		empagliflozin was made for minimum 1500 tablets which compensated to the meager loss found during the coating process, thus resulting in 100% content of empagliflozin in the process. Morcover, the tablet loss for the in process testing was almost 6-8% of the total trial size (1500 tablets) before it reaches to the stage of active coating. Whereas active coating solution of empagliflozin was made for minimum 1500 tablets which compensated to the meager loss found during the coating process, thus resulting in 100 % content of empagliflozin in the process. Firm has aslo submitted in process analysis sheets for the trial batches.
3.2.S.5	COAs of reference/working standard used for the analysis of drug substances by M/s Wilson, shall be submitted.	Submitted
3.2.P.2.2.1	Justification shall be submitted for performing dissolution test of Metformin HCl on one time point only in pharmaceutical equivalence studies.	Firm has submitted new Pharmaceutical equivalence studies wherein Dissolution of Mtformin HCl has been performed for complete extended release profile.
3.2.P.5.1	In contrast to the innovator drug product literature firm has proposed one-time dissolution limits for Metformin HCl. Justification shall be submitted in this regard.	Firm has submitted revised drug product specifications wherein Dissolution of Mtformin HCl has been declared for complete extended release profile.
3.2.P.5.3	Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	Firm has submitted COA oftrial batches wherein Dissolution of Mtformin HCl has been performed for complete extended release profile.
3.2.P.5.4	Submitted COA of trial batches declare dissolution results for Metformin HCl at only one-time point only. Justification shall be submitted in this regard.	

Decision: Registration Board approved the applications of EMP-MET XR 5/1000mg Tablet, Emp-Met XR 25/1000 mg Tablet, Emp-Met XR 12.5/1000 mg Tablet & Emp-Met XR 10/1000 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

37.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 36361 dated 14-12-2022
	Details of fee submitted	Rs.30,000/- dated 23-11-2022
	The proposed proprietary name / brand name	**Wardy Plus XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains; Empagliflozin …… 5mg Metformin Hydrochloride (extended release) ……. 1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs
Remarks of Evaluator:		
Decision: Approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**s		
38.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 3134 dated 02-02-2023
	Details of fee submitted	Rs.75,000/- dated 27-01-2023
	The proposed proprietary name / brand name	**Zonalene-B Forte Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of Gel Contains: Adapalene…01mg Benzoyl Peroxide…25mg
	Pharmacotherapeutic Group of (API)	**Adapalene:** Retinoids WHO ATC Code: D10AD03 **Benzoyl Peroxide:** Topical Antibiotics WHO ATC Code: D10AE01
	Reference to Finished product specifications	Innovator's specifications

39.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 3135 dated 02-02-2023
	Details of fee submitted	Rs.75,000/- dated 27-01-2023
	The proposed proprietary name / brand name	**Zonalene-B Forte Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of Gel Contains: Adapalene…03mg Benzoyl Peroxide…25mg
	Pharmacotherapeutic Group of (API)	**Adapalene:** Retinoids WHO ATC Code: D10AD03 **Benzoyl Peroxide:** Topical Antibiotics WHO ATC Code: D10AE01
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3**	➢ Submit evidence of availability of required manufacturing facility for "Gel" dosage form..	Submitted
2.	**1.6.5**	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted , issued by the relevant regulatory authority of country of origin.	Submitted
3.	**3.2.P.5.1**	➢ Submitted drug product specifications have been referred to USP while section 1.5.6 declare it as per Innovator. ➢ Justification shall be submitted for the Assay limits of Benzoyl peroxide declared as 90%-125%. ➢ Reference for the limits of pH test shall be submitted.	➢ We have changed the drug products specifications from USP to innovator in the respective section. ➢ The assay limits of the benzoyl peroxide was taken from the official monograph of benzoyl peroxide in united states pharmacopeia. ➢ The measured pH for the Innovator drug was 5.87. While the limits for the pH was taken from separately official monographs of benzoyl peroxide Gel in the USP and Adapalene Gel in the USP.

4.	**3.2.P.7**	➢ Details of the material of construction i.e., type, grade etc... of the container closure system shall be submitted.	Construction of the material is plastic (polypropylene) and sealed with aluminium
5.	**3.2.P.8.1**	➢ Storage statement shall be as per the recommendations for products to be marketed in Zone IV conditions	Storage condition has been updated.
6.	**3.2.P.8.3**	➢ Justification shall be submitted for submitting stability studies data of two batches only. ➢ Stability studies of 6th month time point shall be submitted.	➢ We have selected two batches as per minutes of 293rd meeting of registration broad, Implementation of common Technical Document 3.2.P.8 Stability, clause (a) Aerosol and anu other specializes preparations 500. ➢ 6th Month stability studies data has been submitted.

Decision: Registration Board approved the applications of Zonalene-B Forte Gel (0.1%/2.5%) & Zonalene-B Forte Gel (0.3%/2.5%). The firm shall submit fee of Rs. 7,500/- for each strength for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK**
	Name, address of Manufacturing site.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 1622 dated 12-01-2021
	Details of fee submitted	Rs.50,000/- dated 28-07-2020
	The proposed proprietary name / brand name	**Pentom 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Pentosan Polysulfate Sodium…100mg
	Pharmacotherapeutic Group of (API)	Urologicals, other urologicals, ATC code: G04BX15
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr. No.	Section #.	Deficiencies	Firm's response
1.	**1.6.5**	Valid GMP certificate or Drug Manufacturing License of the drug	Firm has submitted License validity certificate for drug substance

		substance manufacturer shall be submitted, issued by the relevant regulatory authority.	manufacturer issued by Directorate of Drug Control Chennai, India declaring validity of License upto 09-06-2024.
2.	**3.2.S.4.1**	Justification shall be submitted for the Assay limits of 95.0% 105.0% for the drug substance.	Firm has submitted revised drug substance specifications with Assay limits of 98-102%
3.	**3.2.S.4.2**	Evidence of availability of HPLC equipped with RI detector shall be submitted.	Shimadzu HPLC equipped with RID detector and auto injector is installed in Genome Pharmaceutical Quality control laboratory.
4.	**3.2.S.4.3**	• Composition of "placebo solution", used in the performance of specificity test shall be clarified. • Specificity test has been performed without spiking impurities or exposing the test solution to stress conditions. This performance shall be justified with reference to ICH Q2 (R1) guidelines and USP chapter <1225>.	Firm has submitted forced degradation studies.
5.	**3.2.S.5**	Clarification shall be submitted regarding Assay limits of 95.0% 105.0% for the working standard.	Firm has submitted revised COA of working standard
6.	**3.2.P.2.2.1**	Following shall be established for the sake of Pharmaceutical equivalence: • The starting material used to manufacture the proposed PPS should be the same as that used to manufacture the drug substance for the reference product. • The molecular weight distribution between the proposed PPS and the drug substance in the reference product should be comparable. Moreover, the overall structural properties or characteristic fingerprints of the proposed PPS, including (but not limited to) the degree of sulfation, sodium content, Raman and IR spectra, should be equivalent to that of the drug substance in the reference product. • Equivalence of monosaccharide building block composition and chain branching of the proposed PPS should be equivalent to the drug substance in the reference	Firm has submitted following characterisation studies from the drug substance manufacturer performed against reference product Elmiron: • The structural confirmation of (Pentosan Polysulphate sodium) PPS is achieved by HNMR, CMR, UV, FTIR spectroscopic techniques. • Molecular weight determination for three batches of Pentosan Polysulfate Sodium along with reference product • Sulfate content by conductometric titration

		product, with respect to the molecular properties, including (but not limited to) xylose units, sulfation pattern, glucuronic acid groups, linkages, and anomeric configurations.	
7.	**3.2.P.5.2**	Analytical method applied for the analysis of dissolution sample has not been mentioned.	Submitted
8.	**3.2.P.5.3**	Specificity test has been performed without spiking impurities or exposing the test solution to stress conditions. This performance shall be justified with reference to ICH Q2 (R1) guidelines and USP chapter <1225>.	Firm has submitted forced degradation studies.
9.	• Submitted BMR declares the content of "Pentosan Polysulfate sodium as 111mg per capsule, whereas the label claim of applied product is 100mg per capsule. Clarification shall be submitte n this regard.		• Drug substance was dispensed by potency adjustment on as is basis since Pentosan polysulphate sodium contains 10% water (max)

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

a. Deferred cases

41.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-19/2014-Lic. from Secretary CLB for issuance of DML, declaring availability of "tablet general section".
	Dy. No. and date of submission	Dy.No 33039 dated 16-12-2021
	Details of fee submitted	Rs.30,000/- dated 01-12-2021

	The proposed proprietary name / brand name	**Celezib 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib ……100mg
	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules with red and blue ACF rings and blue color OPC mark
	Pharmacotherapeutic Group of (API)	Non-steroidal Anti inflammatory (NSAID)
	Reference to Finished product specifications	BP
	Proposed Pack size	20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Celecoxib 100 mg capsules, hard by M/s Macleods Pharma UK Limited, approved by MHRA of UK.
	For generic drugs (me-too status)	Celbex 100mg capsule by M/s Getz Pharma (Pvt) Limited Reg. No. 028694
	GMP status of the Finished product manufacturer	New DML was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 29-08-2018, including Capsule general section
	Name and address of API manufacturer.	M/s AARTI DRUGS LIMITED, Plot No. E-21/22, M.I.D.C, Tarapur, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches:(KM-1102215, KM-1102315, KM-1102415)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Comparative dissolution profile has been established against the Clebex capsule of M/s Getz Pharma in three buffer mediums i.e., ph1.2, pH 4.5 & ph 6.8 with acceptable results.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s AARTI DRUGS LIMITED, Plot No. E-21/22, M.I.D.C, Tarapur, Maharashtra, India		
API Lot No.	Ceb/10040077		
Description of Pack (Container closure system)	Alu-PVC		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20CRn010	21CRn007	21CRn008
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	12-2020	07-2021	07-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. (New Section)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.14850/2020/DRAP-AD-VIII (I&E) dated 16/10/2020 is submitted wherein the permission to import different APIs including for the purpose of test/analysis and stability studies is granted. • AirWay Bill No. 176-26046624 Dated: 21/12/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• HPLC system digital log has been submitted excluding for the intial time point analysis.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response

1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	Submitted GMP certificate is of another site of AARTI drugs ltd (PLOT NO. W-60(B)W-61(B)W-62(B)W-71(B)W-72(B)W-73(B),MIDC, Tarapur Thane, India), instead of the site (Plot No. E-21/22, M.I.D.C, Tarapur, Maharashtra, India) from which drug substance has been imported.
3.2.S.6	Drug substance is of USP standard whereas reference standard of BP grade has been submitted.	As the drug substance is available in both USP and BP and have same specifications and analytical procedure. Drug product is available only in BP so we chosen BP standard and used it for analysis.
3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted.	• Firm has submitted Pharmaceutical equivalence report against the Celebrex capsule of M/s Getz, wherein instead of dissolution test of batch release, CDP study results have been submitted.
3.2.P.3.5	Submitted process validation protocol does not include sampling plan.	Process validation protocol including sampling plan has been submitted.
3.2.P.8.3	• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Raw data sheets for complete stability studies shall be submitted. • Submitted analytical record does not reflect the performance of system suitability test during Assay analysis as recommended by BP monograph of Celcoxib capsules.	• Firm has submitted copy of commercial invoice# SAMP/1002//20-21-23/10/2020 frrom M/s AARTI drugs ltd., in the name of islam Pharma for the 2.5 Kg of Celecoxib. The submitted invoice is not attested by DRAP I&E office. • Firm has also submitted copy of Air WayBill. • Firm has performed system suitability test by establishing the RSD of standard replicates, while BP monograph recommends performance of system suitability with the help of impurity standards.

Decision of 321st meeting: Deferred for submission of valid GMP certificate issued by the relevant regulatory authority for the drug substance manufacturer.

Firm's response: Firm has submitted GMP certificate issued by FDA Maharashtra, india valid upto 27-05-2025.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

42.	**Name and address of manufacturer/ Applicant**	**"M/s Genix Pharma (Pvt.) Ltd., 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**
	Brand Name + Dosage Form + Strength	Laxetil Solution.

	Composition	Each 5ml Contains: Lactulose ……..… 3.335g OR Each 15ml Contains: Lactulose ……10g
	Diary No. Date of R & I & fee	Duplicate Dossier
	Pharmacological Group	Laxative
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	120ml, 240ml, 300ml, 400ml: As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Lactusure Syrup of Medisure Laboratories Pakistan.
	GMP status	**Conclusion:** In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other CGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at a **satisfactory level of compliance with cGMP guidelines as of today**. The management was also suggested to further strengthen stability and analytical sections."
	Remarks of the Evaluator	Submit source & stability studies of applied of three batches conducted by manufacturer of API.
	Decision of 291st meeting of Registration Board.	Deferred for submission of COA, GMP of API manufacturer and stability studies of three batches of API conducted in accordance with zone IV-A conditions.
	Submission by the firm.	• Firm has submitted GMP certificate for ***M/s Lacsa (pty) Limited, 72 Ballantrae Road, Merebank, Durban, 4052, Kwa-Zulu Natal, South Africa*** issued by SAPHRA dated 02-06-2023 wherein active substance Lactulose by chemical synthesis is mentioned. It is further mentioned that the standard of Good Manufacturing Practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7). • Firm has also submitted real time and accelerated stability studies of three batches for the active substance. Real time conditions are 30˚C ± 2˚C / 65% ± 5%RH for 48 months and accelerated condition are 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches (P2246, P2247 & P2248). • They also submitted COA of the drug substance.
	Remarks of the Evaluator.	Fee verification is required as it was not mentioned in the agenda. In case of fee for local registration is submitted, differential fee for import shall be submitted.
	Decision of 331st meeting: Deferred for following; • Evidence of submission of dossier along with its verification from R&I Section. • Evidence of submission of fee for instant application its verification from Budget & Accounts Division.	
	Firm's response: Incharge R&I has verified the submission of instant application vide Diary no. 24656 dated 15-12-2017. Firm has also submitted copy of deposit slip no. 0577513 for submission of Rs. 20,000/- fee.	
	Decision: Approved. Firm shall submit differential fee for imported source of bulk drug before issuance of registration letter.	

43.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Arostein 225mg Sachet
	Composition	Each Sachet Contains

		Erdostetine…225mg
	Diary No. Date of R& I & fee	Dy No. 16040: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mucodox 225mg Sachet by Vision Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 329th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting along with evidence of approval of required manufacturing facility/section from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Firm's response: Firm has submitted following: • Regularization of layout plan letter issued by Secretary CLB dated 05-10-2021 declaring Dry Powder/Sachet (General Section). • GMP certificate issued on basis of inspection conducted on 17-06-2021. • Reference of approval of applied formulation in name of M.s Vision Pharma in 292nd meeting on basis of "Erdotin 225mg Sachet approved by AIFA of Italy.	
	Decision: Approved on basis of "Erdotin 225mg Sachet approved by AIFA of Italy.	

44.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	GMP Certificate issued on 28-03-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000782 (Formulation) renewed on 03-02-2019 which the approved sections are mentioned including section namely Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26329 dated 19-09-2022.
	Details of fee submitted	PKR 30000 dated: 18-10-2022 bearing Deposit Slip No. 968710443987

	The proposed proprietary name / brand name	**PYTOL-X Tablet (665 mg)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release tablet contains: Paracetamol … 665mg USP Specs.
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OSTEOMOL 665 PARACETAMOL modified release Film **Coated tablet** TGA Australia.
	For generic drugs (me-too status)	Panadol-XR M/s GSK Paksitan Limited, Karachi.
	Name and address of API manufacturer.	**Paracetamol (B.P):** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 GMP Certificate No .(Not legible) issued on 19-03-2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **(Batch No. PGP14-37, PGP14-38, PGP14-39)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Panadol Extended Release 665mg Tablets by performing quality tests including Identification, weight variation, Hardness, Assay, Dissolution. CDP has been performed against the same brand that is Panadol Extended Release 665mg Tablets Batch No. 2S6L manufacturing date December 2021 in, Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Paracetamol:** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 GMP Certificate No.(Not legible) issued on 19-03-2019		
API Lot No.	**PGP21-549**		
Description of Pack (Container closure system)	The proposed pack size of PYTOL-X Tablet 665 mg is 2x 10's in Alu—Alu Blister/Aluminum File.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	AER-001	AER-002	N/A
Batch Size	5000 TABLETS	5000 TABLETS	N/A
Manufacturing Date	02-2022	02-2022	N/A
Date of Initiation	15-02-2022	15-02-2022	N/A
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 **GMP Certificate No.(Not legible)** issued on 19-03-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not Required**
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with summary data sheets , however, the chromatograms, raw data sheets are not submitted at every point of

	chromatograms, Raw data sheets, COA, summary data sheets etc.	sampling/testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Following Documents are found deficient:

1. The GMP certificate of API manufacturer is issued on 19-03-2019, therefore, provide updated legible copy of GMP certificate of API manufacture in the light of guidance document.
2. Firm has applied for extended release un-coated tablets while the innovator Product OSTEOMOL 665 PARACETAMOL is modified release Film Coated tablet , therefore, submit evidence of un-coated tablet (Paracetamol 665mg) in Relevant Regulatory authorities.
3. Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product.
4. Provide Proposed Pack Size of Product.
5. The chromatograms, raw data sheets are not submitted at every point of sampling/testing.
6. Justification shall be submitted for same reading throughout the stability studies of both chambers as per submitted data logger record.

Reply of the Firm :

Sr No	Deficiencies/Short-coming	Answers
1	Provide updated legible copy of GMP certificate of API manufacturer.	Updated GMP Copy of API manufacturer has been attached here
2	Evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board shall be submitted. As the applied formulation in reference regulatory authorities is approved as "Film coated" tablets while the applicant has applied as un-coated tablets.	It is a typographical mistake to written in composition, Product has been formulated as film coated tablet In process testing record at film stage, filled BMR has been attached here
3	Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator/ reference product.	Qualitative Composition of Pytol-x is same as Innovator Product so Compatibility studies has been not performed Formulation of reference product has been attached here.
4	The chromatograms, raw data sheets shall be submitted for every point of sampling/testing during stability study.	chromatograms, raw data sheets for every point of sampling/testing during stability study has been attached here
5	Justification shall be submitted for same reading (Temperature & Humidity) throughout the stability studies of both chambers as per submitted data logger record.	Stability chamber 21 CFR Compliance software Audit trail has been attached here which shows all changes with date and time

Decision: Registration Board deferred the case for following reasons:

i. The applicant shall submit detail of measures adopted by other countries (whether RRA or non-RRA) to mitigate the risk of toxicity associated with over-dose of above-mentioned product.

ii. The applicant shall also submit detail of practicable measures which will be adopted after grant of marketing authorization to prevent the risk of toxicity associated with over-dose of above-mentioned product.

Firm's response: Firm has submitted documenst regarding Measures adopted to mitigate the risk of toxicity associated with over dose of paracetamol from TGA Australia & Finland along with commitment to adopt same measures. Frm has also submitted to the conditions of approval for Panadl extend 665mg tablets granted b registration Board in its 331st meeting.

Decision: Keeping in view the approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (WLA; WHO Listed Authority) Authorities and PICs member countries, Registration Board approved the instant application along with following conditions as approved previously by registration board in its 331st meeting for applied formulation:

a) Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

b) Manufacturer will perform process validation of first three batches of the product as per the commitment submitted in the registration application.

c) Complete finished product specifications (in tabulated form) will be annexed with the registration letter.

d) To mitigate the risk due to toxicity associated with overdose of Paracetamol Extend Tablet 665mg, registration letter will be issued with following additional conditions/ statements:

"Following conditions should appear on label of the product in bold and conspicuous manner:

- **For adults, the highest recommended dose of Panadol Extend Tablet 665mg is 1.3 g and the maximum daily dose is 4 g (i.e., 2 tablets 3 times a day with highest dose of 6 tablets a day).**
- **Paracetamol Extend Tablet 665mg should not be used as an alternative to Panadol/ Paracetamol Tablet 500mg without prior consultation with Physician/ Pharmacist."**

e) Above-mentioned conditions will also be included in advertisement of the product and for this purpose, recommendation will be forwarded to Pharmacy Services Division, DRAP.

f) To ensure compliance with the above-mentioned conditions, the applicant will be advised to conduct training programmes for the health care providers and submit biannual compliance reports to PE&R Division subsequent to issuance of registration.

45.	**Name and address of manufacturer/ Applicant**	**M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.**
	Brand Name + Dosage Form + Strength	**CARB 40/5 Tablets**
	Composition	Each film coated tablet contains: Telmisartan ……40mg Amlodipine as Besylate….5mg
	Diary No. Date of R & I & fee	Dy. No. dated 29-11-2010, Rs. 8,000/- dated 29-11-2010 (Challan photocopy dated 12-10-2010), Dy. No. dated 17-01-2017, Differential fee Rs. 12,000/- dated 03-01-2017 submitted vide deposit slip No.0569397 dated 01-12-2016. "Duplicate dossier, verification of R & I for initial and differential fee submission along with fee challans required".
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 40mg/5mg of M/s Atco laboratories, Karachi. Registration No. 098764
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised the label claim as: Each uncoated bi-layered tablet contains: Telmisartan ……40mg Amlodipine as Besylate….5mg, along with revision of composition/master formulation and manufacturing outlines.

		• Firm revised finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • With regard to availability of bi-layered compression machine, the firm replied as: We have the machine/equipment ZPW23 II (I.D # NQFC-P & M-TCM2) for the manufacturing of bi-layered tablets and are manufacturing several bi-layered tablets in this section. The firm provided copy of purchase invoice for ZPW23 compression machine and Good Declaration (GD-I) certificate. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.9226887964 for revision of finished drug product specifications. • The firm submitted remaining fee of Rs: 22,500/- vide online deposit slip No.933234663.
	Decision of 321st meeting: Deferred for verification of R & I record of initial submission of registration application as the same could not be verified by the R & I Section	
	Firm's response: The case was referred by Inchareg PEC to R&I section for confirmation of original submission of application from record, to which Assitant Director Admin-IV has replied as under: "It is intimated that the firm has submitted the original acknowledgenment receipts shoiwng original R&I sign/stamp of product Carb 5/40 tab. Dated 29-11-2010. The firm has also attached the acknowledgement receipts of other strengths of same product i.e., 5/20, 10/20, 10/40 and 5/80 as sane date having the same original sign / stamp. However, entry could not be made in R&I register, inadvertently. Through the R&I sign / stamp of product Carb 5/40 tab are same and authentic please."	
	Decision: Registration Board considering the declaration from R&I section regarding submission of the registration application decided to approve the instant application as per following label claim: **"Each uncoated bi-layered tablet contains:** **Telmisartan ……40mg** **Amlodipine as Besylate….5mg"**	

46.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No 30769 dated 31-10-2022.
	Details of fee submitted	Rs.30,000/- vide challan No. 2890223452 dated 20-07-2022.
	The proposed proprietary name / brand name	**VOMITA 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syrup contains: Ondansetron hydrochloride ……4mg

	Pharmaceutical form of applied drug	White color round shaped film-coated tablet, packed in Alu-Alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists, anti-emetics
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	3 × 10's
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	ZOFRAN® (Ondansetron hydrochloride) oral solution, 4mg/5ml (contains 5 mg of ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron per 5 mL in amber glass bottles of 50 mL with child-resistant closures) by Novartis pharmaceuticals, Co. (USFDA approved)
	For generic drugs (me-too status)	Xortron Oral Solution (Each 5ml contains: Ondansetron hydrochloride dihydrate eq to ondansetron: 4mg), Registration No. 102367 of M/s McOlson Research Laboratories, Sheikhupura.
	GMP status of the Finished product manufacturer	New DML (DML No. 000924 granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Evidence of section approval.	Liquid syrup (General) Section approval granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.
	Module-II (Quality Overall Summary)	Firm has submitted Quality Overall Summary: Product Dossier details as per WHO QOS-PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Incomplete stability studies summary data sheets of drug substance submitted: Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 06 & 09 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AOND-17002, AOND-17003 & AOND-17004)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its composition, formulation development, pharmaceutical equivalence, comparative dissolution profile, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zofran 8mg tablet of M/s GSK, Pakistan by performing quality tests such as Identification, Assay, Dissolution and Uniformity of dosage unit. Comparative dissolution profile (CDP) has been performed against the same brand that is Zofran 8mg tablet of M/s GSK, Pakistan in Acid media (pH 1.0-1.2), Acetate Buffer pH 4.5 & Phosphate Buffer (pH 6.8). Discrepancy in data observed. Details given below in remarks column.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.		
API Lot No.	AOND-21001		
Description of Pack (Container closure system)	1 × 10's in Alu-Alu blisters, packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-01	T-01
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-01-2022	01-01-2022	01-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted M/s Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru, Karnataka, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted Quantity received 1kg as mentioned in CoA of API by drug product manufacturer. Date of received 12-2021.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Incomplete submission as raw data sheets, summary data sheets, content uniformity data and dissolution data not provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Previous decision: Registration Board in its 326th meeting d deferred the case for clarification / submission of following points to which firm has responded as mentioned below against each.

Firm's response:

Sr. No.	Section	Observation	Reply by the firm
1.	**1.5.2**	• The strength/label claim provided is not in accordance with the innovators product that is: each 5ml syrup contains: ondansetron (as hydrochloride dihydrate) ……. 4 mg	Firm has submitted revised label claim as under: **EACH 5ML SYRUP CONTAINS:** Ondansetron (As hydrochloride dihydrate) ……. 4 mg
2.	**1.5.4**	• The pack size mentioned as 3×10's	Revised pack size declared is as per SRO.
3.	**1.5.10**	• The applied dosage form mentioned as: white color round shaped film-coated tablet, packed in alu-alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.	Firm has submitted revised dosage form as oral syrup.
4.	**1.6.5 (B)**	• No evidence of approval of manufacturing facility of api by concerned regulatory body submitted.	Submitted Copy of License issued by Drug Control Department Govt. of Karnataka valid upto 13-02-2025.
8.	3.2.S.4.1	• Specifications for drug substance provided by the drug product manufacturer has two different values for residue on ignition test. clarification shall be submitted.	Firm has susbmitted revised sepcifications as per USP monograph.
9.	3.2.S.4.2	• Analytical procedure (signed) for the drug substance by the drug product manufacturer shall be submitted.	Submitted
10.	3.2.S.7.3	• Incomplete long term stability studies summary data sheets (only for 6 & 9 months) for the drug substance have been submitted by the firm.	Firm has submitted stability study data as per Zone Iva.
11.	3.2.P.1	• description & composition of the drug product part is not provided.	Submitted.
12.	3.2.P.2.1	• The sub-parts, 3.2.p.2.1.1 (drug substance) & 3.2.p.2.1.2 (excipients), under components of the drug product are not submitted. compatibility studies of the drug substance(s) with excipients not provided as qualitative composition	Submitted

		of the formulation is not similar to innovator / reference product.	
13.	3.2.P.2.2.1	• The API quantity given without considering salt factor of the api. as evident from the trial batches bmr attached at 2.3.r.1, the quantity of api has been dispensed/mentioned without salt factor calculation.	Firm has submitted revised calculations as per theroatical factor and determined potency
14.	3.2.P.2.2.1	• In formulation development, the quantity given per bottle (60ml) is 0.04gm, which comes out to be 0.67mg/ml or 3.35mg/5ml while the applied composition is 4mg/5ml.	
15.	3.2.P.2.2.1	• The firm has mentioned that pharmaceutical equivalence conducted against market's comparator product namely onseron 4mg/5ml oral solution. however, summarized test results of pharmaceutical equivalene submitted is against zofran 4mg/5ml oral solution.	Firm has submitted pharmacueitcal equivalence studies against Onseron Syrup of M.s Horizon Pharma.
16.	3.2.P.2.5	• The microbiological enumeration tests & tests for specified micro-organisms declared as "not applicable". however, the same are given in usp official monograph of ondansetron oral solution as microbial enumeration tests <61> and tests for specified microorganisms <62>.	Firm has submitted revised drug product specifications as per USP monograph.
17.	3.2.P.3.2	• in batch formula, for 1000 l batch size, the quantity of ondansetron hcl given as 0.4kg and also without considering salt factor calculation. with this quantity, composition/strength of product comes out to be 2mg/5ml of ondansetron hcl while the applied composition is 4mg/5ml of ondansetron (as hcl dihydrate).	Firm has submitted revised calculations as per theroatical factor and determined potency
19.	3.2.P.5.1	• in drug product specifications, the deliverable volume specification mentioned as "in-house". however, the same is given in official monograph (usp) for ondansetron oral solution under usp general chapter <698> deliverable volume.	Firm has referred that limits were selected in accordance with USP general chapter <698>.
20.	3.2.P.5.2	• analytical procedure of drug product not provided by the firm. the firm has submitted extract of usp for ondansetron oral solution.	Submitted detailed drug product analyhticalprocedure.
21.	3.2.P.5.4	• coa of 03 trial batches submitted in which the assay for trial batch t-03	Firm has submitted rectified COA.

		given as 100.20%, while coa of same batch has assay result as 101.49%.	
22.	3.2.P.8.1	• in the stability summary and conclusions, the firm has stated that trial batches were kept under real time stability conditions in stability chambers on 01-01-2022 and under accelerated stability conditions on 13-05-2021.	Firm has submitted revised stability summary sheets.
23.	3.2.P.8.3	• in the stability study data, the mfg. and exp. date of t-02 batch mentioned as 01-2023 and 01-2024 respectively. while stability studies dated provided from 01-01-2022 to 01-06-2022.	
24.	3.2.P.8.3	• provide raw data sheets, summary data sheets, audit trial reports and digital data logger record for temperature & humidity monitoring of stability chambers (both real and accelerated) in support of stability studies performed of the trial batches.	Submitted
25.	3.2.P.8.3	• the wavelength mentioned in chromatogram/hplc reports submitted is 328nm, however, as per analytical procedures submitted and official monograph of the product, the wave length for assay determination is 216nm.	Firm hassubmitted analytical record as per chromaytogrpahic conditions in USP monograph.
26.	3.2.P.8.3	• the time intervals among the chromatograms/hplc reports of standard and samples analysis, mostly vary from 1-3minutes. while the runtime for each analysis is 15 minutes, with retention time of peaks for all standards and samples as 3.770-3.774 (approx. 3.77). clarification and scientific justification is required in this regard, as to how such intervals among chromatograms possible, with aforementioned peak retention times and run time of the analysis performed.	Firm has referred the said time as time for processing for printing of chromatograms.
27.	3.2.R.1.1	• the bmr of trial batches (t-01, t-02 & t-03) submitted are blank bmrs, having no details of actual execution of production/manufacturing of the trial batches, such as personnel signatures, in-process checks, reconciliation record, time intervals for different manufacturing steps, quantities dispensed etc.	Submitted.

28.		approval of api/ dml/gmp certificate of api manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
29.		documents for the procurement of api with approval from drap (in case of import)	Firm has submitted copy of commercial invoice attested by AD I&E DRAP Karachi, dated 18-11-2021.
30.		compliance record of hplc software 21cfr & audit trail reports on product testing.	Not submitted
31.		record of digital data logger for temperature and humidity monitoring of both stability chambers.	Submitted.

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

47.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan **contract manufacturing by** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Awacol 1MIU IV Injection
	Composition	Each Vial Contains: Colistimethate Sodium (Lyophilized Powder) ……1MIU
	Diary No. Date of R& I & fee	Dy. No.12455 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Antibiotic (polymyxin)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s Usawa Pharmaceuticals was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Did not provide chemical name of the API at serial No. 03. Later on, submitted it. • Had mentioned Colistimethate Sodium eq. to Colistimethate and mentioned its weight as 85.68mg in master formula. Then, mentioned

		Colistimethate Sodium…1MIU and revised 85.68mg to 90mg (for 7% water contents and 4%overage). Then, revised Colistimethate Sodium…90mg (for 7% water contents and 4%overage to Colistimethate Sodium…80mg. But the label claim in the revised documents is Colistimethate Sodium eq. to Colistimethate….1MIU. Then, once again submitted the label claim "Each Vial Contains: Colistimethate Sodium (Lyophilized Powder)…1MIU" shall be considered. • Also mentioned water for injection, and lyophilization process. • Added packing process to the manufacturing outlines. • Revised brand Awacol 11MU to Awacol 1MIU. • Submitted Rs. 7500 (challan- 557752858924)
	Decision of 321st meeting: Registration Board deferred the case for submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.	
	Firm's response: Firm has submitted BMRs form M/s Bio labs wherein applied formulation has been manufactured by way of lyophilization.	
	Decision: Approved as per following label claim: **Each Lyophilized Vial Contains:** **Colistimethate Sodium …… 1MIU**	
48.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	LEXO 120mg Capsule
	Composition	Each Capsule contains: Fexofenadine HCl……....120mg
	Diary No. Date of R& I & fee	Dy.No.26400 ;(09-12-2019);Rs.20,000/-
	Pharmacological Group	Antihistamine
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	10's and 20's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Exo Capsule English Pharmaceuticals
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Evaluation by PEC	Reference product could not be confirmed
	Decision of 294th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Firm has submitted revised composition as following against the reference mentioned hereafter: "Each Film Coated Tablet Contains: Fexofenadine HCl…120mg" Approval status of product in Reference Regulatory Authorities: Approved by TGA of Australia Me-too status: Fanoxin Tablets 120mg "M/s Jawa Pharmaceutical (Pvt) Ltd, Lahore (Reg.#052778)	
	Decision: Approved as per following label claim: **"Each Film Coated Tablet Contains:** **Fexofenadine HCl…120mg"** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product dosage form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
49.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**

	Brand Name +Dosage Form + Strength	LEXO 180mg Capsule
	Composition	Each Capsule contains: Fexofenadine HCl……...180mg
	Diary No. Date of R& I & fee	Dy.No. 26402 ;(09-12-2019);Rs.20,000/-
	Pharmacological Group	Antihistamine
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	10‘s and 20‘s; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Exo Capsule English Pharmaceuticals
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Evaluation by PEC	Reference product could not be confirmed
	Decision of 294th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm’s response: Firm has submitted revised composition as following against the reference mentioned hereafter: "Each Film Coated Tablet Contains: Fexofenadine HCl…180mg" Approval status of product in Reference Regulatory Authorities: Approved by TGA of Australia Me-too status: Afex 180mg tablet of M/s Shaheen Pharma (Reg. # 064319)	
	Decision: Approved as per following label claim: **"Each Film Coated Tablet Contains:** **Fexofenadine HCl…180mg"** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product dosage form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
50.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	MYCO Gel 2%w/w
	Composition	Each tube contains: Miconazole Nitrate……..2%
	Diary No. Date of R& I & fee	Dy.No. 24672 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Pharmacological Group	Antiinfective/ Antiseptic
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	20g tube & as per SRO
	Approval status of product in Reference Regulatory Authorities.	(MHRA Approved)
	Me-too status	Miconit Oral Gel 2% of M/s Bio-Labs (Reg. # 054776)
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Evaluation by PEC	
	Decision of 293rd meeting: Deferred for the revision of label claim as per innovator’s.	
	Firm’s response: Firm has submitted following revised label claim as per Innovator: **“**Each gm contains: Miconazole …….. 20mg”	
	Decision: Approved as per following label claim: **“Each gm contains:** **Miconazole …….. 20mg”** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
51.	**Name and address of manufacturer / Applicant**	**Simz Pharmaceuticals (Pvt) Ltd., 574-575, Sunder Industrial Estate, Raiwind Road, Lahore Contract manufactured by Friends Pharma (Pvt) Ltd, 31-Km,**

		Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	**Sunday Injection 5mg/1ml**
	Composition	Each ml contains:- Cholecalciferol (vitaminD3)……5mg (vitamin-D analogue)
	Diary No. Date of R& I & fee	Dy No. 9399 31-7-2013 PKR 50000/- (31-7-2013)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3GOOD (ANSM France approved)
	Me-too status	Vitamin D3injection by Ameer Pharma
	GMP status	
	Remarks of the Evaluator	Reminder 02-05-2018 Letter 04-4-2018 •Latest GMP inspection report of the manufacturer which should have been conducted within a period of last 1 year. •Description of container closure has not been submitted. •Detail of already registered products on contract manufacturing. •Evidence of approval of manufacturing facility / section of the manufacturer by Licensing division •The application on Form 5 has been submitted by M/s Friends Pharma, while the applicant is M/s Simz Pharma.
	Previous Decision 284	Registration Board in its 284th meeting decided as under: Registration Board deferred the case for further deliberation
	Evaluation by PEC AD(PEC-XII)	Deficiencies already communicated to the firm, further product is approved in ANSM France and in Me-Too 600,000 IU(15mg) of cholecalciferol has used according to the Registered product Data.
	Previous Decision (295)	Deferred for submission of followings: • Latest GMP inspection report of the manufacturer which should have been conducted within a period of last 1 year. • Description of container closure has not been submitted. • Detail of already registered products on contract manufacturing. • Evidence of approval of manufacturing facility / section of the manufacturer by Licensing division • The application on Form 5 has been submitted by M/s Friends Pharma, while the applicant is M/s Simz Pharma.

	Evaluation by PEC AD	

S#	Query	Response
1.	Latest GMP inspection report of the manufacturer	Last inspection report dated 08/3/2019 panel recommended renewal of DML.
2.	Description of container closure has not been submitted.	The container is 1 ml glass ampoule
3.	Detail of already registered products on contract manufacturing	Firm claims that No registered product is there on contract
4.	Evidence of approval of manufacturing facility / section of the manufacturer by Licensing division	The general lyophilized injection and liquid injection(General) is present
5.	The application on Form 5 has been submitted by M/s Friends Pharma, while the applicant is M/s Simz Pharma	The application on Form 5 has been submitted by the applicant M/s Simz Pharma instead of M/s Friends Pharma

	Decision of 312th meeting: Deferred for evaluation of the applied formulation with reference to the Pharmacopoeial monographs available for "Cholecalciferol injection".
	Firm's response: Firm has submitted that no pharmacopoeial monograph is available so kindly grant us the registration on Innovator specifcations.
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

52.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Inventor Pharma (Pvt.) Ltd. Plot No K/196 S.I.T.E. (SHW) Phase II, Karachi, Pakistan.**
	Name, address of Manufacturing site.	M/s Inventor Pharma (Pvt.) Ltd. Plot No K/196 S.I.T.E. (SHW) Phase II, Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	--
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 20056 dated 13-07-2022
	Details of fee submitted	Rs.30,000/- dated 01-03-2022
	The proposed proprietary name / brand name	**TERB-IN-H CREAM 10gm**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Terbinafine hydrochloride……10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal ((D01BA02)
	Pharmaceutical form of applied drug	A smooth white colored cream filled in Alu Tubes.
	Reference to Finished product specifications	JP Specs

	Proposed Pack size	1 x 10g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil 1% Cream (MHRA Approved)
	For generic drugs (me-too status)	TERBIMAX CREAM 10mg of M/s Mexitech Pharma (Pvt) Ltd.
	Name and address of API manufacturer.	**Terbinafine Hydrochloride**: Cipla-Kurkumbh Cipla Limited. ***Address:*** Plot No. D-22, MIDC Industrial Area, Kurkumbh Village, Taluka-Daund, District-Maharashtra, India. Tel. No. +91 -22-25754354
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product TERBIMAX CREAM 10mg of M/s Mexitech Pharma (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Terbinafine Hydrochloride**: Cipla-Kurkumbh Cipla Limited. ***Address:*** Plot No. D-22, MIDC Industrial Area, Kurkumbh Village, Taluka-Daund, District-Maharashtra, India. Tel. No. +91 -22-25754354

API Lot No.	Terbinafine Hydrochloride: LDX180025		
Description of Pack (Container closure system)	HMHDPE Bags tied with LDPE Fasteners, Fiber Drum.		
Stability Storage Condition	Real time: 325°C ± 2°C / 60% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 60 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	15000 Tubes	15000 Tubes	15000 Tubes
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	10-07-2021	17-07-2021	17-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator: Following shall be submitted:

- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP (in case of import).
- GMP status of the firm
- Evidence of approval of manufacturing facility

Decision of 331st meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response: Firm has submitted following:

- GMP certificate no. NEW-WHO-GMP/CERT/KD/103280/2021/11/37083 issued by FDA Maharashtra valid upto 15-08-2024.
- Copy of commercial invoice attested by AD I&E DRAP, Karachi dated 22-06-2021 for 1Kg of Terbinafine HCl.
- Copy of GMP certificate issued by Additional Director DRAP, Karachi issued on basis of inspection conducted on 13-09-2022 declaring availability Cream/Ointment (geenral) section

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
53.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi**
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30772 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 21/07/2022
	The proposed proprietary name / brand name	**Throtsin 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Azithromycin as dihydrate …….250 mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet (Oral)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Zithromax 250mg Tablet by M/s Pfizer Pharma.
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 vide letter No.F.2-3/2016-Lic.
	Section approval	Tablet General Section
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceuticals Co., LTD, No.9 xingye street, Shijiazzhuang economic and technological development zone, Hebei province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (200407021,200407022,200407023)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc for drug product and drug susbatnce.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Guolong Pharmaceuticals Co., LTD China		
API Lot No.	220207001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	20-08-2021	20-08-2021	20-08-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Previous Decision: Registration Board in its 321st meeting d deferred the case for clarification / submission of following points to which firm has responded as mentioned below against each.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1	Provide analytical method verification studies including specificity, precision and accuracy for drug substance performed by drug product manufacturer.	Submitted
2	Since the excipients used in the formulation are different from the innovator's / reference product, therefor compatibility studies of excipients with drug substance are required along with the relevant documents.	Firm has submitted drug excipient compaitibility studies.
3	Details of section 3.2.P.4 have not been provided in the submitted dossier.	Submitted.
4	Justification is required since you have not performed UNIFORMITY OF DOSAGE UNITS as described in official monograph of USP. Therefore, you are required to submit revised specifications along with the applicable fee.	Firm has submitted revised drug product specifications, without submission of applicable fee.
5	Submit detail analytical method used for drug product instead of submitted copy of USP monograph.	Submitted.
6	Provide complete protocols for analytical method verification studies for drug product including details of preparations and concentrations of all the standard solutions in mg/mL used in accuracy and repeatability studies.	Submitted.
7	Provide COA of reference standard actually used in the product development.	Submitted.
8	Submit stability study data along with raw data sheets in a proper sequence with separators to segregate the stability data for each time point for all the three batches.	Firm has submitted re-organized stability studies data.
9	Justification is required since at 3rd month time point of stability studies (accelerated) for batch number T61 and T62 and T63, the retention time and peak of chromatogram is exactly same for sample analysis.	Firm has submitted chromatograms for stability analysis of each trial batch.
10	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and	Firm has submitted following:

	the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	• GMP certiifcat issued by State Food And Drug Administtration China valid upto 14-11-2025. • Copy of commercial invoice attested by AD I&E DRAP, Karachi dated 18-07-2021 for 10 Kg of Azithromycin. • Analytical record for stability studies. • Data logger for stability chambers.
10	Provide complete batch manufacturing record along with the calculations for potency adjustment considering the assay value of Azithromycin Dihydrate as per submitted COA.	Submitted
11	Provide data of pharmaceutical equivalence and comparative dissolution profile against reference / innovator's product along with the relevant documents.	Firm has submitted Pharmaceutical Equivalence and CDP studies against the Zetamax tablet of M/s Pfizer.
12	Scientific justification is required since as per USP monograph of Azithromycin Tablet, the injection volume is 100uL while as per submitted dossier the injection volume Is 20uL. Moreover, provide evidence of use of column oven having capacity to maintain the column temperature at 50°C as per USP requirement.	Firm has submitted revised analytical procedure as per USP monograph declaring that earlier it was mistakenly written

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

54.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi**
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30773 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 21/07/2022
	The proposed proprietary name / brand name	**Throtsin 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Azithromycin as dihydrate …….500 mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet (Oral)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Zithromax 500mg Tablet by M/s Pfizer Pharma.
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 vide letter No.F.2-3/2016-Lic.
	Section approval	Tablet General Section
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceuticals Co., LTD, No.9 xingye street, Shijiazzhuang economic and technological development zone, Hebei province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (200407021,200407022,200407023)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc for drug product and drug susbatnce.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Guolong Pharmaceuticals Co., LTD China		
API Lot No.	220207001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	20-08-2021	20-08-2021	20-08-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Previous Decision: Registration Board in its 321st meeting d deferred the case for clarification / submission of following points to which firm has responded as mentioned below against each.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1	Provide analytical method verification studies including specificity, precision and accuracy for drug substance performed by drug product manufacturer.	Submitted
2	Since the excipients used in the formulation are different from the innovator's / reference product, therefor compatibility studies of excipients with drug substance are required along with the relevant documents.	Firm has submitted drug excipient compaitibility studies.
3	Details of section 3.2.P.4 have not been provided in the submitted dossier.	Submitted.
4	Justification is required since you have not performed UNIFORMITY OF DOSAGE UNITS as described in official monograph of USP. Therefore, you are required to submit revised specifications along with the applicable fee.	Firm has submitted revised drug product specifications, without submission of applicable fee.
5	Submit detail analytical method used for drug product instead of submitted copy of USP monograph.	Submitted.
6	Provide complete protocols for analytical method verification studies for drug product including details of preparations and concentrations of all the standard solutions in mg/mL used in accuracy and repeatability studies.	Submitted.
7	Provide COA of reference standard actually used in the product development.	Submitted.
8	Submit stability study data along with raw data sheets in a proper sequence with separators to segregate the stability data for each time point for all the three batches.	Firm has submitted re-organized stability studies data.
9	Justification is required since at 3rd month time point of stability studies (accelerated) for batch number T61 and T62 and T63, the retention time and peak of chromatogram is exactly same for sample analysis.	Firm has submitted chromatograms for stability analysis of each trial batch.
10	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted following: • GMP certiifcat issued by State Food And Drug Administtration China valid upto 14-11-2025. • Copy of commercial invoice attested by AD I&E DRAP, Karachi dated 18-07-2021 for 10 Kg of Azithromycin. • Analytical record for stability studies. • Data logger for stability chambers.

	o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	
10	Provide complete batch manufacturing record along with the calculations for potency adjustment considering the assay value of Azithromycin Dihydrate as per submitted COA.	Submitted
11	Provide data of pharmaceutical equivalence and comparative dissolution profile against reference / innovator's product along with the relevant documents.	Firm hassubmitted Pharmaceutical Equivalence and CDP studies against the Zetamax tablet of M/s Pfizer.
12	Scientific justification is required since as per USP monograph of Azithromycin Tablet, the injection volume is 100uL while as per submitted dossier the injection volume Is 20uL. Moreover, provide evidence of use of column oven having capacity to maintain the column temperature at 50ºC as per USP requirement.	Firm has ubmitted revised analytical procedure as per USP monograph declaring that earlier it was mistakenly written

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

55.	**Case deleted due to repetition**	
56.	Name, address of Applicant / Marketing Authorization Holder	**M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate valid up to 12-01-2025
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate specifying availability of Liquid Injection Vial section (General).
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3532 dated 07-02-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2022
	The proposed proprietary name / brand name	**MetroWel Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Metronidazole …..…… 500 mg
	Pharmaceutical form of applied drug	Sterile Solution for intravenous infusion
	Pharmacotherapeutic Group of (API)	Nitro-imidazole Antimicrobials
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Flagyl Infusion of Sanofi Aventis
	Name and address of API manufacturer.	M/s Hubei Hong Yuan Pharmaceuticals technology Co. Ltd. Address: 126 # Dabeishan Road, Industrial and Economic Development Zone Luotian County, Huanggang Cirt, Hubei, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Well & Well Pharma (Pvt) Ltd. Plot No.7 Street S-8 National Industrial Zone RCCI Rawat
Manufacturer firm	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	MetroWel Infusion

	Decision of 333rd meeting: Deferred for the clarification of applying in two different container/closure systems as the same formulation is already registered in glass vial.
	Firm's response: We M/s Indus Pharma (Pvt) Ltd Hereby, would like to clarify that we currently hold registration for the aforementioned product in glass vials. However, we have submitted an application for the same formulation in a different container ciosure system specifically BFS as separate drug product requiring new Registration on applied container closure as part of our business expansion strategy. This is to meet the marketing demand Furthermore, the formulation applied in a similar container is also available internationally.
	Decision: Registration Board while considering the approval of applied formulation by reference regulatory authorities i.e., US FDA in Plastic container closure system approved the instant application as separate registration.

57.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 09-03-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on basis of inspection conducted on 09-03-2020 declares availability of Tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 24077 dated 25-08-2022 Rs.30,000/- dated 23-08-2022
	The proposed proprietary name / brand name	**Terb-C 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine HCl …..250mg
	Pharmaceutical form of applied drug	Uncoated tablet
	Pharmacotherapeutic Group of (API)	Anti fungal agent
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil tablet Approved by US FDA
	For generic drugs (me-too status)	Lamisil tablet of Novartis Reg. 013209
	Name and address of API manufacturer.	M/s Saptagir Laboratories Pvt Ltd Sy.no parts of 27, 46 & 50 to 56, Ananthasagar (Vill) chegunta (Mandal), Medak (Dist.), Telanga, India-502 247
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the Lamisil tablet of M/s Novartis has been submitted
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA

Manufacturer of API	M/s Saptagir Laboratories Pvt Ltd Sy.no parts of 27, 46 & 50 to 56, Ananthasagar (Vill) chegunta (Mandal), Medak (Dist.), Telanga, India-502 247		
API Lot No.	TH0020121		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months)		
Batch No.	TE250T004	TE250T005	TE250T005 TE250T006
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the below cited shortcomings.

Firm's response:

Section #	Observations	Firm's response

1.3	Latest GMP inspection report of the drug product manufacturer shall be submitted, conducted within last three years.	Firm ha ssubmitted panel inspection report dated 22-02-2022 recommending renewal of DML.
1.5.2	Label claim for strength of Terbinafine shall be submitted as per Innovator drug product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted following revised label claim: Each Tablet Contains: Terbinafine HCl eq. to Terbinafine …..250mg
3.2.S.4.4	Submit COA of Terbinafine HCl of relevant batch used for manufacturing of drug product stability batches, from the drug substance manufacturer & drug product manufacturer.	Submitted.
3.2.P.2.2.1	Submit CDP studies in three dissolution mediums of pH 1.2, 4.5 & 6.8 performed against the reference product.	Suubmitted against Lamisil 250mg tablet.
3.2.S.7	• Long term stability studies data for shall be submitted till claimed shelf life.	Submitted
3.2.P.8.3	Submit following: • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Data of stability batches supported by respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• GMP certificate valid till 20-02-2024 issued by DCA, Government of Telangana. • Copy o fcommercial invoice attested by AD I&E DRAP, Islamabad dated 30-04-2021. • Analytical record for drug product stability studies along with audit tril nad data logger record for stability batches.

Decision: Approved as per following label claim:
"Each Tablet Contains:
Terbinafine HCl eq. to Terbinafine …….. 250mg"

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

58.	Name, address of Applicant / Importer	GlaxoSmithKline Pakistan Limited,35 Dockyard Road, West Wharf, Karachi 74000, Pakistan
	Details of Drug Sale License of importer	License No: 1180 Address: F-268 S.I.T.E. Karachi Validity: 19.02.2022 Status: License to stock, exhibit for sale, distribute and sell by way of whole-sale. Renewal: Firm has submitted an acknowledgement receipt of renewal dated 01.02.2022
	Name and address of marketing authorization holder (abroad)	M/s. Piramal Pharma Limited, Plot No. 67-70, Sector-II, Pithampur, District-Dhar, M.P 454 775

	Name, address of manufacturer(s)	M/s. Piramal Pharma Limited, Plot No. 67-70, Sector-II, Pithampur, District-Dhar, M.P 454 775
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized Export CoPP certificate (No.04) dated 14.05.2022 issued by Food and Drug Administration, India. Firm has also submitted original, legalized Australian CoPP certificate (No.21/1171) dated 21/10/2021 issued by Department of Health, Therapeutic Goods Administration for evidence of product approval in SRA markets and confirmation of Free sale. The CoPP confirms GMP status of the manufacturing site through periodic inspection every year. According to the CoPP, the exporting country is Australia and the name and address of applicant is GlaxoSmithKline Australia Pty Ltd. 1061 Mountain Highway BORONIA VIC 3155 Australia and importing requesting country is Pakistan.
	Details of letter of authorization / sole agency agreement	Firm has submitted sole agency confirmation from Piramal Pharma Limited. The letter states that the Product License Holder and manufacturer i.e., M/s. Piramal Pharma Limited authorizes GlaxoSmithKline Pakistan Limited as their sole agency for supply and distribution of Kozenis 150mg Tablet in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 205211 dated 10/09/2021
	Details of fee submitted	PKR 75,000/-: 24.06.2021
	The proposed proprietary name / brand name	**Kozenis (Tafenoquine) 150mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains 188.2mg of tafenoquine succinate (equivalent to 150mg of tafenoquine)
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Antimalarial (106635-81-8)
	Reference to Finished product specifications	The product is an originator brand. GSK Specs.
	Proposed Pack size	The pack contains 2 tablets
	Proposed unit price	NA – The supply will primarily be made through a supranational agency (e.g., UNICEF) or through direct procurement by the Government authorities or through a tender.
	The status in reference regulatory authorities	Krintafel (USFDA Approved), Kozenis (TGA Approved) Firm has submitted evidence of product approval in reference regulatory authorities dated 10.09.2021
	For generic drugs (me-too status)	NA

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH M4 CTD with justification for a new drug (originator brand)
	Name, address of drug substance manufacturer	Piramal Pharma Limited Survey Numbers 7-70, 70/1 and 70/2 Digwal Village Kohir Mandal Sangareddy District 502 321 Telangana India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data comprising of General Information, Structure, Manufacture, Characterisation, Control of Drug Substance, Reference Standards or Materials, Container Closure System, Stability.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at for up to 48 months at 30°C/75% RH or for up to 6 months and accelerated at 40°C/75% RH.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Clinical Study Reports comprising of Reports of Biopharmaceutic Studies, Bioavailability (BA) Study Reports, Comparative BA and Bioequivalence (BE) Study Reports, Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Child-resistant aluminum foil blister strip
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at for up to 48 months at 30°C/75% RH or for up to 6 months and accelerated at 40°C/75% RH.
Evaluation by PEC:		
Decision of 317th meeting: Deferred for following: • Evaluation & presentation of complete details regarding Pharmacological, Pharmacodynamic & clinical indications, contra-indications etc of the applied product. • Approval and availability status of the product in reference regulatory authorities and other countries with malaria prevalence. • Opinion of Directorate of Malaria Control regarding tentative rollout plan of the drug product.		

Firm's response:
Opinion of the Directorate of Malaria Control (DoMC)-Pakistan on the use of tafenoquine 150mg tablet, with expert commentary on its registration:

The Directorate of Malaria Control (DoMC)-Pakistan enthusiastically supports and propose a rollout plan for tafenoquine 150mg tablet, informed by extensive international and Pakistan- based research findings. Studies such as those conducted by LIanos-Cuentas et al. (2019) and Commons et al. (2018) have demonstrated the remarkable efficacy of tafenoquine in preventing relapse of Plasmodium vivax malaria, thereby offering a promising solution to the challenges posed by this form of the disease.

Research efforts in Pakistan, such as the work of Khan et al. (2020), have provided valuable insights into the epidemiology of malaria in the region and underscored the urgent need for innovative treatment approaches. Additionally, studies by Malik et al. (2017) have highlighted the burden of P. vivax malaria in Pakistan and emphasized the importance of effective radical cure strategies.

Tafenoquine's unique single-dose regimen and long-lasting efficacy represent significant advancements in simplifying treatment protocols and enhancing patient adherence, as underscored by research by Dow et al. (2020). These attributes offer a remarkable opportunity to streamline malaria control efforts in Pakistan, as supported by findings from local studies such as those conducted by Khattak et al. (2018).

However, it is essential to **consider potential side effects** associated with tafenoquine. While generally well-tolerated, adverse effects such as gastrointestinal disturbances, headache, and dizziness have been reported in clinical trials, as documented in studies by LIanos-Cuentas et al. (2019) and Dow et al. (2020), Close monitoring and prompt management of adverse reactions are crucial to ensure the safe and effective use of tafenoquine in malaria control programs.

Furthermore, **international research papers**, including the work of White et al. (2018) and Baird (2018), have provided critical insights into the efficacy, safety profile, and side effect profile of tafenoquine in diverse malaria-endemic settings. Their findings underscore the importance of comprehensive risk-benefit assessments and vigilant pharmacovigilance measures in the registration and deployment of tafenoquine.

While acknowledging the importance of addressing potential side effects, including adverse effects and cost considerations, we draw confidence from research efforts such as those by Lacerda et al. (2019) and the insights gained from both Pakistan-based and international studies. The Directorate is committed to supporting initiatives aimed at monitoring drug interactions, ensuring affordability, and fostering collaboration, as advocated by White et al. (2018), to safeguard the effectiveness of tafenoquine in combating malaria in Pakistan and globally.

In **CONCLUSION**, the Directorate of Malaria Control (DoMC)-Pakistan firmly believes that the introduction of tafenoquine 150mg tablet holds great promise in advancing our fight against malaria, as evidenced by compelling findings from international and Pakistan-based research endeavors. We stand ready to champion its integration into malaria control programs in Pakistan and are committed to realizing its full potential in improving health outcomes for Individuals at risk of malaria.

PROPOSED ROLLOUT PLAN

Keeping in view the importance of Tafenoquine in the radical cure of vivax malaria and elimination of malaria from Pakistan, the Tafenoquine must be introduced for routine management of vivax malaria. The introduction of Tafenoquine will be linked to WHO recommendations for its use in adult and pediatric vivax cases and approval for use in Pakistan by DRAP

As discussed earlier, prescription of Tafenoquine is linked with the G6PD mandatory testing. Currently the Directorate of Malaria Control Pakistan (DoMC)-Pakistan has launched a G6PD testing pilot project in 9 high malaria burden districts across 4 provinces through the support of Asia Pacific Malaria Elimination Network (APMEN) and Malaria Medicines Venture (MMV). A very comprehensive training program for Provincial Master Trainers and selected Health Facilities focal persons for the use of G6PD analyzers was conducted here in Islamabad during January 07-09, 2024.

Following are some **salient features** of Tafenoquine rollout plan in Pakistan

1. As Tafenoquine is linked to G6PD testing, in initial phase, after approval, Tafenoquine piloting will be done in the districts where G6PD testing is already available.

2. Updating the national treatment guidelines to include Tafenoquine in the routine vivax malaria case management.

3. Expansion of G6PD testing and relevant trainings to all the tertiary and secondary level health facilities across Pakistan followed by availability of Tafenoquine in these health facilities.

4. Further expansion of G6PD testing and relevant trainings to all the primary healthcare facilities across Pakistan coupled with Tafenoquine availability.

5. Prohibition on the over-the-counter sale of Tafenoquine in Pakistan.

7. Involving private sector and provision of Tafenoquine to only those health facilities where G6PD testing is available and being routinely conducted.

- Firm has also referred to the Krintafel tabket approved by US FDA.

Decision: Registration Board while considering the opinion of the "Directorate of Malaria Control (DoMC)-Pakistan" and approval of applied formulation in US FDA decided to approve the instant application.

Furthermore, Registration Board, keeping in view the sensitivity of the product specially in G6PD deficient patients, decided to:

- **restrict the dispensing/sale of the instant product to "Hospital only" having facilities of G6PD testing as condition of registration letter.**
- **issue an advisory to the Health Care Commissions in the light of proposed rollout plan for Pakistan to ensure the G6PD testing and relevant trainings to all the health facilities across Pakistan where Tafenoquine is being dispensed.**

59.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020.
	Evidence of approval of manufacturing facility	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020 declares availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Dy. No. and date of submission & Details of fee submitted	Dy.No 23832 dated 23-08-2022 Rs.30,000/- dated 20-06-2022
	The proposed proprietary name / brand name	**Jargin Duo 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl …..500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Diampa-M 12.55/500 of M/s Getz

		pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.		
API Lot No.	Metformin Hydrochloride: MEF/11020485		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	EGMF-12.5/500/T001	EGMF-12.5/500/T002	EGMF-12.5/500/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	10/2021	11/2021	11/2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Decision: Registration Board deferred the case for submission of reply to the below cited shortcomings.

Firm's response:

Section #	**Observations**	**Firm's response**

1.6.5	Submit valid DML/GMP certificate of drug substance manufacturers, issued by relevant regulatory authority of country of origin.	Valid GMP certificate till 20-06-2026 issued by Food & Drugs Control Administration Gujarat, India has been submitted.
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	It is a typographic error, Empagliflozin is slightly soluble in water.
3.2.S.4.1	Justify the variation in drug substance specifications between drug substance manufacturer and M/s Pharmedic laboratories for Empagliflozin	Firm has submitted revised drug substance specifications.
3.2.S.4.3	Analytical method verification studies of drug substances shall be submitted from M/s Pharmedic laboratories.	Submitted
3.2.S.4.4	• Submit COA of relevant batch of Metformin HCl & Empagliflozin used for preparation for drug product trial batches, from drug substance manufacturer. • Submitted COA of Empagliflozin form M./s Pharmedic Laboratories declare drug substance manufacturer as M/s Shanghai YST Pharma Co. Ltd, China whereas 3.2.S part has been submitted from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Justification shall be submitted in this regard.	Firm has submitted COA of relevant batch drug substance. The submitted invoice attested by AD I&E Lahore dated 24-06-2021 is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd
3.2.S.7.3	Long term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV conditions.	Submitted
3.2.P.5.1	Justification shall be submitted for dissolution limits of 30 minutes with reference to the innovator drug product literature.	Firm has submitted revised drug product specifications.
3.2.P.5.4	Justification shall be submitted for not performing "Uniformity of Dosage Unit" test by way of "Content Uniformity" for Empagliflozin.	Firm has ubsmitted revised raw data sheets with performance of content uniformity test.
3.2.P.8.3	Submit following: • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of comemrial invoice no. YST21121 attested by AD I&E DRAP, Lahore dated 24-06-2021 for 181gm of Empagliflozin. The invoice is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Data logger record submitted.

Decision: Deferred for clarification regarding manufacturer of drug substance used for manufacturing of drug product stability batches since submitted copy of commercial invoice is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd.

60.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-

		A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-09-2021 specifying Capsule (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 23372 dated 18-08-2022 Rs.30,000/- dated 28-02-2022
	The proposed proprietary name / brand name	**Gerdmax 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Eq. to Esomeprazole…20mg
	Pharmacotherapeutic Group of (API)	Capsule
	Pharmaceutical form of applied drug	Proton pump inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Nexum 20 mg cap of M/s Getz pharma (Reg.# 033891)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC 8.5% pellets as per Zone IVa conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Nexum capsule of M/s Getz. Firm has submitted CDP results of their product against the innovator's product Nexum capsule of M/s Getz in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.		
API Lot No.	EMZ046605		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-185	T-190	T-191
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of inspection conducted on 14-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-02-2023 specifying 20Kgs of Esomeprazole Magnesium EC pellets 8.5% from M/s Vision Pharmacueticals.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.S.4.1	Justify the limits of ± 10% for Assay test of Esomeprazole Magnesium EC pellets, while considering it as drug substance.	
3.2.P.1.2	Justify the proposed weight/capsule of Esomeprazole Mg 8.5% EC pellets against the label claim of 20mg Esomeprazole.	
3.2.P.2.2.1	Justification shall be submitted for not performing CDP and Pharmaceutical equivalence studies against the Innovator product.	
3.2.P.8.3	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
--	Complete batch manufacturing record pf stability batches shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's response:

Section #	Observations	Firm's response
3.2.S.4.1	Justify the limits of ± 10% for Assay test of Esomeprazole Magnesium EC pellets, while considering it as drug substance.	Drug substance emanufacturer of Esomeprazole magnesium EC pellets 8.5% has ste their assaylimit ± which have the product label claim (7.65% - 9.35%). Firm has also set their Assay test limit of Esomeprazole magnesium EC pellets
3.2.P.1.2	Justify the proposed weight/capsule of Esomeprazole Mg 8.5% EC pellets against the label claim of 20mg Esomeprazole.	Firm ha ssubmitted factor calculation against the molecular weight.
3.2.P.2.2.1	Justification shall be submitted for not performing CDP and Pharmaceutical equivalence studies against the Innovator product.	At the time of study innovator drug product was not availabel in the market.
3.2.P.8.3	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Submitted
--	Complete batch manufacturing record pf stability batches shall be submitted.	Submitted

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

61.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**

	Name, address of Manufacturing site.	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi "
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21537 dated 22-10-2019
	Details of fee submitted	Rs.50,000 dated 21-10-2019
	The proposed proprietary name / brand name	**Azilsart 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Azilsartan …….. 10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blocker.
	Reference to Finished product specifications	Manufacturer specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azilva Tablet approved by PMDA of Japan.
	For generic drugs (me-too status)	N/A
	GMP status	GMP certificate issued on basis of inspection conducted on 28-08-2019.
	Name and address of API manufacturer.	M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., Chem & API's Industrial Zone, Linhai, Zheijiang , China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	Relevant information has been submitted including Analytical method verification studies & batch analysis.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability studies data has been submitted as per Zone IV a conditions.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the reference product of "Azilva Tablets" in three dissolution mediums has been submitted with acceptable level of f2 results
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., Chem & API's Industrial Zone, Linhai, Zheijiang , China.
API Lot No.	C1011-0148104
Description of Pack (Container closure system)	Alu-PVC blister foil

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	TF-01	TF-02	TF-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	07-2018	07-2018	07-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd–4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu 's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (ZJ20180032) issued by China Food & Drug Administration, valid upto 14-03-2023 for M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., China
3.	Documents confirming import of API etc.	Not submitted. Firm has submitted copy of Fed Ex courier slip, from which details of shipment could not be verified.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

REMARKS OF EVALUATOR

Sr. No.	Section #.	Deficiencies	Response
Module II			
1.	**2.3. S.7**	Long term stability studies shall be submitted as per Zone IVa conditions.	
2.	**2.3.P.3.2**	Relevant information shall be submitted as per template of QOS.	
3.	**2.3.P.3.3**	A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified.	
Module III			
4.	**3.2.S.4**	Analytical record for the analysis of drug substance performed by the drug product manufacturer shall be submitted.	Analytical record including HPLC chromatograms & raw data sheets have been submitted.
5.	**3.2.S.5**	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of working standard from M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., China has been submitted.
6.	**3.2.S.7**	Long term stability studies shall be submitted as per Zone IVa conditions.	Long term stability studies have been submitted as per Zone IVa conditions.
7.	**3.2.P.2.2.1**	equivalence of the applied drug shall be th the innovator / reference / comparator ults of all the quality tests (mentioned in any acopoeia or section 3.2.P.5.1 of this f the developed formulation and the eference / comparator product shall be discussed. shed product analytical method describes for the dissolution analysis, whereas CDP been performed by applying UV etric method.	Pharmaceutical equivalence studies have been submitted against the innovator product of "Azilva" tablets. HPLC record for the performance of CDP studies has been submitted.
8.	**3.2. P.3.5**	A brief description of process validation including the proposed protocol shall be described	Process validation protocol has been submitted.
9.	**3.2. P.5**	Submitted finished product specifications does not include test of content uniformity for Azilsartan.	Firm has submitted analytical record for the performance of Content Uniformity test.
10.	**3.2. P.8**	Documents confirming import of API, approved by DRAP I&E office shall be submitted. cord of HPLC software 21CFR & audit trail uct testing shall be submitted.	tted that they have procured the sample of API . Firm has submitted FedEx courier slip in this f commercial invoice no. HY181115-1 (not AP), has been submitted for 0.5 Kg of Azilsart.

Decision of 307th meeting: Registration Board deferred all three applied strengths of Azilsart 40mg tablet (Azilsartan), Azilsart 20mg tablet (Azilsartan) & Azilsart 10mg tablet (Azilsartan) for following reasons:

- Status of the applied formulation in reference regulatory authorities other than PMDA of Japan.
- Comparative evaluation of the indications, dosage other clinical particulars between "Azilsartan Kamedoxomil tablet" & "Azilsartan tablet".

Firm's response:

- The applied molecule is available only in PMDA of Japan as azilva tablet.
- Moreover, firm has submitted following comparison:

S. No.	COMPARATIVE EVALUATION OF STUDY OF CLINICAL DATA		
	Clinical DATA	**Azilsartan**	**Azilsartan Medoxomil**
1	**Metabolism**	Directly enter as an active. No need of conversion from inactive to active form. Does not require hepatic metabolism by CYP2C9. Thus more effective in patients with hepatic compromise.	Azilsartan medoxomil is a pro-drug. It absorbs in gut and biotransforms in liver converting it into its active metabolite azilsartan by enzyme CYP2C9.
2	**Indication**	For the treatment of hypertension	For thr treatment of Hypertension
3	**Dosage**	20 mg - 80 mg	40 mg - 80 mg
4	**Pharmacokinetics:**		
	Bioavailability	60% approximately	60%
	Elimination half-life	11 hours	11 hours
	Peak plasma concentration	1.5 to 3 hours	2 to 3 hours
5	**Adverse effects**	orthostatic hypotension, nausea, muscle spasm, dizziness, asthenis, fatigue, cough, diarrhea	ypotension/orthostatic hypotension, ausea, diarrhea, fatigue, muscle spasm, postural dizziness,

Decision of 312th meeting: Registration Board deferred for further deliberations upon strength of applied formulations wrt USFDA approved formulation.

Firm's response:

- In Pakistan 40 and 80 mg is registered as Azilsartan Medoxomil while USFDA also launched 20 mg strength as Edarbi.
- 10 mg Azilsartan tablet is for children while 20mg is starting dose for Adults.
- Azilva Tablet is available in 3 strength 10, 20 and 40 as Azilsartan.

Sr.#	PARAMETERS	AZILSARTAN	AZILSARTAN MEDOXOMIL
1	**Metabolism**	Directly enter as an active. No need of conversion from inactive to active form. Does not require hepatic metabolism by CYP2C9. Thus, more effective in patients with hepatic compromise.	Azilsartanmedoxomil is a pro-drug. It absorbs in gut and bio transforms in liver converting it into its active metabolite azilsartan by enzyme CYP2C9.
2	**Indication**	For the treatment of hypertension	For the treatment of Hypertension
3	**Tablet Strength**	10,20 and 40 (Azilva Japan) Applied strength (10.20 and 40)	20,40 and 80 (Edarbi USA) Registered strength (40 and 80)
4	**Dosage**	20 mg - 80 mg (Adult) 10mg(children)	40 mg - 80 mg
5	**Drug Interaction**	Azilsartan base has no such type of Hyperkalemia No dosage adjustments required in hepatic and renal compromised patients	1. Since the use of potassium supplements and potassium-containing salt substitutes with an angiotensin II receptor antagonist (e.g., azilsartanmedoxomil) can increase the potential for hyperkalemia, some clinicians have suggested that concomitant administration of these agents with azilsartan medoxomil should be avoided. 2.AzilsartanKmedoxomil is converted into active Azilsartan by Liver Enzyme (Cytochrome P450 (CYP) 2C9

			3. Should be used with caution with NSAID and other Potassium Drugs
6	**Residual Solvents in Raw Material**	Class 1 Solvents: Dichloromethane Class 3: Ethanol, Isopropanol	Class 1 solvents: Dichloromethane Class 2 Tetrahydrofuran Class 3 Solvents: Methanol, Acetone, Ethyl Acetate

- Azilsartan innovator is AZILVA available in 10mg, 20mg and 40mg.
- Azilsartan medoxomil innovator is available as EDARBI 20mg, 40mg and 80mg.

Decision of 313rd meeting: Registration Board approved Azilsart 40mg Tablet & Azilsart 20mg Tablet as per Innovator's specifications.

- Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
- Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.
- Moreover, Registration Board deferred the application of Azilsart 10 mg tablets for further deliberation upon the indication & dosage of 10mg strength in paediatric population.

Firm's response: Firm has submitted a research article titled as "Pharmacokinetics of a Single Dose of Azilsartan in Pediatric Patients: A Phase 3, Open-Label, Multicenter Study" which concludes as under:
"In line with previous population PK data, our study suggests that pediatric patients weighing less than 50 kg may have approximately 2-fold greater exposure to Azilsartan than those weighing at least 50 kg at the same dose, whose exposure to Azilsartan is comparable to that in healthy adults. Azilsartan treatment was feasible, with no u5nexpected safety signals observed in this study in pediatric patients with hypertension. A larger phase 3 study is ongoing to explore specific efficacy in this patient group."

Decision of 316th meeting: Deferred for submission of complete "PIL/SMPc" of the innovator drug product**.**

Firm's response:

The Patient Information Leaflet (PIL) for Azilva Tablet 10mg/20mg/40mg is exclusively available in Japanese language. We have included the complete PIL as **Annexure-1.** The indications and dosage information provided below are transcribed from the original PIL found on the product packaging. Sections that have been translated are highlighted in yellow within the PIL copy.

Highlight # 1

効能・効果
高血圧
Efficacy/effect
Hypertension

Highlight # 2

用法・用量
通常、成人にはアジルサルタンとして20mgを1日1回経口投与する。年齢、症状により適宜増減されるが、1日最大投与量は40mgである。
Dosage/usage
The usual adult dose is 20mg of Azilsartan administer orally once a day. The dosage may be adjusted as appropriate depending on age and symptoms but maximum daily dose should be 40mg

A copy of Drug Information sheet is also attached as **Annexure-2.** As per drug information sheet Dosing schedule for Azilsartan shall be as follows:

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- Adults: In general, take 20 mg of the active ingredient at a time, once a day. The dosage may be adjusted according to the age or symptoms, but should not exceed 40 mg a day.
  Children aged 6 years old or over: In general, start taking 2.5 mg of the active ingredient at a time, once a day, for children weighing less than 50 kg and 5 mg of the active ingredient at a time, once a day, for children weighing 50 kg or over. The dosage may be adjusted according to the age, weight or symptoms, but should not exceed 20 mg a day for children weighing less than 50 kg and 40 mg a day for children weighing 50 kg or over.

This preparation contains 10 mg of the active ingredient in a tablet. Strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. However, wait at least 8 hours to take the next dose. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

62.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27254 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-FLOX 500mg Tablet**
	Strength / concentration of drug of Active	Each film coated tablet contains

	Pharmaceutical ingredient (API) per unit	Levofloxacin Hemihydrate equivalent to Levofloxacin ……. 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin Tablet 250mg Approved US FDA
	For generic drugs (me-too status)	Leflox tablet 500mg of M/s Getz Pharma
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Leflox Tablet 500mg manufactured by Getz Pharma Pakistan. Firm has submitted CDP results of their product against the Leflox Tablet 500mg in 3 dissolution medias. i.e., Acidic media (pH 1.2), Acetate buffer

		(pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.		
API Lot No.	DC-004-2009013		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-041	TRT-042	TRT-043
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	10-2022	10-2022	10-2022
No. of Batches	03		

63.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27253 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-FLOX 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin ……. 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)

	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin Tablet 250mg Approved US FDA
	For generic drugs (me-too status)	Leflox tablet 250mg of M/s Getz Pharma (Reg. No. 026164)
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Leflox Tablet 250mg manufactured by Getz Pharma Pakistan. Firm has submitted CDP results of their product against the Leflox Tablet 250mg in 3 dissolution medias. i.e., Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.

	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.		
API Lot No.	DC-004-2009013		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-038	TRT-039	TRT-040
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	26-09-2022	26-09-2022	26-09-2022
Date of Initiation	29-09-2022	29-09-2022	29-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate dated 29-07-2021 issued by Sanmen market supervision Administration people,s Republic of China valid for 5 years till 28-07-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of import invoice having batch number DC-004-2009013 and Invoice number LEV201103-L specifying 200Kg of Levofloxacin Hemihydrate attested by AD I&E DRAP dated 25-11-2020 in name of M/s Fahmir Pharma. Firm has also submitted loan letter from M/s Fahmir Pharma for 0.7 Kg of Levofloxacin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision of 333rd meeting: Registration Board deferred the applications of AG-FLOX 500mg Tablet & AG-FLOX 250mg Tablet for submission of reply to above cited shortcomings.

Firm's response:

Section no.	Observations	Firm's response

1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	Submitted
3.2.S.3.1	Copies of the IR spectrum of drug substance, performed by M/s AGM pharmaceuticals shall be submitted.	Submitted
3.2.S.4.2	Analytical procedure from drug substance ,manufacturer shall be submitted.	Submitted
3.2.S.4.3	• Clarification shall be submitted regarding the "placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance. • Submitted analytical method verification studies declare the concentration of Ciprofloxacin in performance of accuracy parameter. Justification shall be submitted in this regard.	Firm has referred diluent solution as placebo. Firm has submitted corrected analytical method verification studies.
3.2.S.4.4	Submitted COA of drug substance from M/s AGM Pharmaceuticals is not signed.	Signed COA is submitted
3.2.S.5	• Submitted COA of working standard is not from the same drug substance manufacturer. Justification shall be submitted in this regard. • Submitted COA of working standard does not declare the Assay value.	Firm has submitted COA of working standard.
3.2.S.7.3	Submitted stability reports shall be signed and stamped form drug substance manufacturer.	Submitted
3.2.P.2.2.1	Justification shall be submitted for not performing CDP and Pharmaceutical Equivalence studies against the innovator drug product. Summited results of CDP shall be justified against the solubility profile of Levofloxacin across the physiological pH range along with literary reference.	Firm has submitted that the selected market brand leader for performance of CDP studies.
3.2.P.3.5	Limits of dissolution test presented in process validation protocol are different form that recommended by USP monograph.	Revised process validation protocol has been submitted.
3.2.P.5.4	Submitted COAs of drug product trial batches from M/s AGM Pharmaceuticals are not signed.	Signed COAs submitted
3.2.P.8.3	• Documents confirming import of drug substance with approval of DRAP I&E office shall be submitted. • Run time of submitted chromatograms for Assay analysis shall be justified against the recommendations of USP monograph. • Raw data sheet for dissolution test performed during stability studies, shall be submitted. • Complete batch ,manufacturing record for stability batches shall be submitted.	Firm has submitted copy of import invoice having batch number DC-004-2009013 and Invoice number LEV201103-L specifying 200Kg of Levofloxacin Hemihydrate attested by AD I&E DRAP dated 25-11-2020 in name of M/s Fahmir Pharma. Firm has also submitted loan letter from M/s Fahmir Pharma for 0.7 Kg of Levofloxacin. Firm has submitted BMRs and raw data sheets for dissolution test.

Decision: Registration Board approved the applications of AG-FLOX 250mg Tablet & AG-FLOX 500mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

64.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27251 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-DOXY 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Doxycycline Hyclate equivalent to Doxycycline……100mg
	Pharmacotherapeutic Group of (API)	Antibiotics (Tetracycline)
	Pharmaceutical form of applied drug	Hard Gelatin Capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x10's, 10x10's 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Doxycycline capsule 100mg M/S Zafa Pharmaceuticals Reg. No. 031290
	Name and address of API manufacturer.	Hebei Jiupeng Pharmaceutical Co., Ltd. No.396 Guangyuan West Street, Yougnian District, Handan City Hubai Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Vibramycin 100mg capsule manufactured by Pfizer Pakistan Ltd. Firm has submitted CDP results of their product against the innovator's product Vibramycin 100mg capsule in 3 dissolution medias. i.e Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hebei Jiupeng Pharmaceutical Co., Ltd. No.396 Guangyuan West Street, Yougnian District, Handan City Hubai Province China		
API Lot No.	A201905008		
Description of Pack (Container closure system)	Light yellowish powder filled in hard gelatin capsule shell no# 2 having yellow color cap and body packed in Alu-Pvc blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRC-035	TRC-036	TRC-037
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-06-22	06-06-22	06-06-22
Date of Initiation	08-06-22	08-06-22	08-06-22
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of import invoice having batch number DC-004-2009013 and Invoice number LEV201103-L specifying 200Kg of Levofloxacin Hemihydrate attested by AD I&E DRAP dated 25-11-2020 in name of M/s Fahmir Pharma. Firm has also submitted loan letter from M/s Batala Pharma for 5 Kg of Levofloxacin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets is submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision of 333rd meeting: Deferred for submission of reply to below cited shortcomings.

Firm's response:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	Submitted
3.2.S.4.2	• Reference shall be submitted for the limits for test of optical rotation. • Justification shall be submitted for not including test of Ethanol in drug substance specifications by M.s AGM Pharmaceuticals.	Firm has submitted revised drug substance analytical procedure.
3.2.S.4.3	• Clarification shall be submitted regarding the "placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance.	Firm has referred diluent solution as placebo.
3.2.P.2.2.1	• Justify the limits of dissolution test applied in Pharmaceutical Equivalence studies.	Firm has referred to the USP monograph
3.2.P.3.5	• Limits of Assay test presented in process validation protocol are different form that recommended by USP monograph. • Submitted process validation protocol does not include Dissolution test at any stage of sampling.	Revised process validation protocol is submitted.
3.2.P.5.2	• Limits of dissolution test shall be justified against the USP monograph of Doxycycline hyclate capsule. • UV spectrophotometric parameter applied for dissolution test shall be justified against the USP monograph of Doxycycline hyclate capsule. • Dissolution parameters applied for dissolution test shall be justified against the USP monograph of Doxycycline hyclate capsule.	Firm has submitted revised analytical procedure as per USP monograph

	• Submitted analytical procedure for Assay test shall be justified against the USP monograph of Doxycycline hyclate capsule.	
3.2.P.5.3	• Analytical method verification studies for Assay test shall be submitted as per USP monograph of Doxycycline hyclate capsule.	Submitted
3.2.P.8.3	• Run time of submitted chromatograms for Assay analysis shall be justified against the recommendations of USP monograph. • Raw data sheet for dissolution test performed during stability studies, shall be submitted. • Complete batch ,manufacturing record for stability batches shall be submitted.	Firm has also submitted loan letter from M/s Fahmir Pharma for 0.7 Kg of Levofloxacin. Firm has submitted BMRs and raw data sheets for dissolution test.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change i as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

65.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27252 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-CIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Ciprofloxacin HCl equivalent to Ciprofloxacin…….. 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic (flouroquinolone)
	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK

	For generic drugs (me-too status)	Novidate 500mg Tablet of M/s Sami Pharma (Reg.No. 011837)
	Name and address of API manufacturer.	Citi Pharma (Pvt) Ltd 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Novidat Tablet 500mg manufactured by Sami Pharma Pakistan. Firm has submitted CDP results of their product against the = Novidat Tablet 500mg in 3 dissolution medias. i.e Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product including accuracy, precision, specificity etc

STABILITY STUDY DATA	
Manufacturer of API	Citi Pharma (Pvt) Ltd 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
API Lot No.	CPH2112137
Description of Pack	Alu-Alu blister .

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-022	TRT-023	TRT-024
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	17-12-2021	17-12-2021	17-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	--
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.31/2023-DRAP (AD-54697225495) dated 09-03-2023 issued by Drug Regulatory Authority of Pakistan valid for 3 years till 02-03-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of local invoice having batch number CPH2112137 and invoice number CP21-10721 specifying 5 Kg of Ciprofloxacin HCl
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision of 333rd meeting: Deferred for submission of reply to above cited shortcomings.

Firm's response:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	Submitted
3.2.S.4.3	• Clarification shall be submitted regarding the "placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance.	Firm has submitted that the selected market brand leader for performance of CDP studies.
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product • Summited results of CDP shall be justified against the solubility profile of Ciprofloxacin across the physiological pH range along with literary reference.	Firm has submitted that the selected market brand leader for performance of CDP studies.
3.2.P.8.3	• Retention time of for Ciprofloxacin in Assay analysis shall be justified against the USP monograph.	Firm has submitted raw data sheets and BMRs.

	• Raw data sheet for dissolution test performed during stability studies, shall be submitted. • Complete batch ,manufacturing record for stability batches shall be submitted.	
Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
66.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals (Pvt.) Ltd., F-95, off hub River Road, S.I.T.E, Karachi.
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals (Pvt.) Ltd., F-95, off hub River Road, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the firm	The firm is granted GMP certificate based on inspection conducted on 28-08-2019.
	Dy. No. and date of submission	Dy. No. dated 27-07-2021
	Details of fee submitted	PKR 50,000/-: dated 08-04-2021
	The proposed proprietary name / brand name	BALOXA 40MG TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baloxavir Marboxil……..40mg
	Pharmaceutical form of applied drug	White to off-white colored, oval shaped film coated tablets, plain on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Antiviral (WHO ATC code: J05AX25)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XOFLUZA ™ (baloxavir marboxil) Tablets 40mg of M/s Genetech USA, Inc (USFDA approved)
	For generic drugs (me-too status)	Not applicable
	Name and address of API manufacturer.	M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd, Address: Jintang Industry Zone, Shaowu City, Fujian Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures

		and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(180801, 180802, 180803)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence and CDP studies could not be performed due to the unavailability of innovator products, justification regarding the comparative studies and innovator pack procurement have been submitted.
	Analytical method validation/verification of product	Method validation studies have been submitted including Linearity, accuracy, precision, robustness and specificity studies.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd, Address: Jintang Industry Zone, Shaowu City, Fujian Province, China		
API Lot No.	200101		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
BALOXA 40MG TABLET			
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	15-10-2020	15-10-2020	15-10-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of last onsite panel inspection for instant dosage form conducted during last two years i.e. EMPOLI (Empagliflozin) 10mg & 25mg Tablets which was presented in 290th meeting of the registration board & hence approved & registered by registration board Date of inspection: 13th June 2019. The inspection report confirms following points The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. FJ20160009 issued by Food and Drug Administration of china valid till 22-02-2021. As per Chinese Government website no more GMP certificates are being issued after December 2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice (Invoice# WIS200028 MAR 18, 2020 with received quantity i.e. 300 g) for the purchase of Baloxavir Marboxil by M/s Fujian Jinsahn Zhundian Pharmaceutical Co., Ltd attested by Assistant Director (I & E) DRAP, dated 25-03-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm
1.	Submit differential fee for the registration of applied product since the applied product since the application was received in R&I section of DRAP after 7th May 2021.	Differential fee deposit slip # 5700633630 of Rs. 25,000/- has been submitted.
2.	The reference product literature showed that the structure and absolute stereochemistry of Baloxavir marboxil is verified by single crystal x-ray determination. The submitted COA from drug substance manufacturer does not contain this test.	The structure and absolute stereochemistry of Baloxavir Marboxil is verified by single crystal x-ray determination is mentioned on COA as polymorphic form, i.e: form I. Revised COA and XPRD Spectra is attached for your reference.
3.	Give a detailed account on polymorphic form of drug substance used in drug product development since several polymorphic forms of drug substance are possible as per reference literature.	Description of polymorphic form of material is defined in DMF (*3.2.S.3.1.9 summary*) as material is polymorphic form I.

4.	Elaborate the test of "Microbial limit Test" mentioned in certificate of analysis of Baloxavir Marboxil.	Microbial examination of non-sterile products is performed as per following USP method given in the texts on Microbial Enumeration Test <*61*>, Tests for Specified Microorganisms <62> and Microbiological examination of non-sterile products (*acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use*) <*1111*>. As per pharmacopeia the acceptance criteria for non-sterile pharmaceutical products based on the total aerobic microbial count (*TAMC*), total yeast and molds count (*TYMC*) and objectionable microorganisms which must be absent and these are called as Microbial Limit Tests. We followed the same practice and set restricted microbiological limits as per SAMI's Specs, that is TAMC: NMT 100 cfu/g, TYMC: NMT 10 cfu/g as well as absence of pathogenic organisms including E. Coli, Salmonella, S. Aureus in our raw material.
5.	The submitted acceptance criteria for release and shelf life specifications are same. Scientific justification is required for adopting such acceptance criteria.	We develop the product specifications according to the general monograph of USP and from the chemistry reviews of USFDA, EMA. In addition, ICH Q6A states that the acceptance criteria are the same from release throughout shelf life of product. Therefore, we have also set the same specification limits for release and shelf life.
6.	The submitted process validation protocol does not describe the critical process steps and controls in defined ranges.	Existing protocol captures the required information and describes critical process parameters along with process controls. However, to make this more elaborative, we have revised these sections and version 2 of protocol is attached.
7.	Since the strategy for product development is planned according to identified QTPP which is based on evaluation of the innovator/reference product therefore, justify the authenticity of product development studies for applied formulation without comparison with innovator/reference product.	The innovator of Baloxavir Marboxil Tablet i.e. XOFLUZA 40mg & 20mg Tablets, already published a detailed characterization of API (*Baloxavir Marboxil*) in FDA chemistry review as well product assessment report of European Medicine Agency (*EMA*). This part of QTPP was derived from FDA chemistry review & EMA assessment report. Appearance of API, its solubility, pKa, partition coefficient, stereoisomerism and polymorphic form etc. were mentioned in detail by the innovator, therefore, all these required details are gathered from literature data. As the reference finished product is presented as immediate-release film-coated tablets for oral administration containing 20mg or 40mg of Baloxavir Marboxil as the active substance, therefore, we have designed our product same as reference product to ensure pharmaceutical equivalency. Product dissolution parameters and other related specification are already disclosed by the manufacturer of the reference product. Due to

		poor solubility of API, to ensure reproducible dissolution results, we have selected micronized grade of API for development of our product as suggested by the reference brand in FDA chemistry review. Due to unavailability of innovator samples, the dissolution profile in different pH mediums i.e., pH 1.2, 4.5 and 6.8 buffers as recommended in WHO for CDP is checked and the release profile found similar to that of innovator product "Xofluza Tablet" in FDA chemistry review publically available. Information related to product packaging, storage and labeling were also gathered from the above mentioned product assessment reports i.e. FDA chemistry review as well product assessment report of European Medicine Agency.

Decision of 316th meeting: Registration Board decided to defer the case for submission of pharmaceutical equivalence and CDP studies with innovator / reference product.

Firm's response: Frim has submitted CDP studies in three physiological pH dissolution medium of ph 1.2, pH 4.5 & pH 6.8 sand pharmaceutical equibvalence report against the reference product of Xofluza 40mg tablet of M/s Shionogi Pharma Co., ltd. Osaka Japan.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

67.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Pvt.) Ltd. 45-KM, Dina Nath, Multan road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt.) Ltd. 45-KM, Dina Nath, Multan road, Lahore. (DML No. 000953)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval letter of capsule section (General) vide No. 1-10/2019-Lic dated 29.04.2022 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 18305 dated 20.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 08374729 dated 20.07.2023
	The proposed proprietary name / brand name	**MAYTAM 0.4mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Tamsulosin HCl……0.4mg (SR pellets 0.2%)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists ATC Code: G04CA02
	Pharmaceutical form of applied drug	White/red hard gelatin capsule in Alu-Alu blister packed in unit carton along with leaflet.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	4's, 5', 6's, 10's, 14's, 20's, 28's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TAMSULOSIN HYDROCHLORIDE 400 MICROGRAMS MR CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Tamsolin 0.4mg Capsule (Reg. No. 050392) M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.). Ltd, Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. TMS365
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. TMS205T, TMS206, TMS208.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Maytam 0.4mg capsule **Reference product:** Tamsolin Capsule, Batch No. 011H. mfg.: 12.22, Exp. 11.24 **manufactured** by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, assay. **CDP:** **pH 1.2:** **pH 4.5:** **pH 6.8:**
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.). Ltd, Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad.		
API Lot No.	202109103A		
Description of Pack (Container closure system)	Off-white granules filled in hard gel caps size 3, body: white, cap: re. Packedin Alu-Alu blister and UC with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 1	Trial 2	Trial 2
Batch Size	1500 caps	1500 caps	1500 caps
Manufacturing Date	11.05.2022	11.05.2022	11.05.2022
Date of Initiation	13.05.2022	13.05.2022	13.05.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 3-26/2019-Addl Dir (QA&LT-I)-56 dated 22.08.2022 issued by DRAP Islamabad is submitted valid till 13.04.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Tamsulosin HCl SR pellets 0.2%** Batch No.: TMS365 Mfg date: 01.04.2022 Exp date: 01.2025 Quantity: 15Kg Invoice No.: 60009 Invoice date: 09.05.2022 Local purchase
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has stated that their HPLC system is not CFR 21 compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2.1	In CDP, Analytical raw data sheets are submitted. The data is not understandable. Time intervals are mentioned as 5 10 15 20 30 minutes; pharmacopoeia gives different time intervals. Data of only Maytam is mentioned in sheets. Details of CDP are required clearly describing the comparison of results in 3 pH media at different time intervals.	The firm vide letter No. nil dated 18.10.2023 has stated that CDP was performed using USP Apparatus II and they are submitting updated data. Firm has submitted revised summary sheets of comparative dissolution profile done at 3 different physiological pH. The results are comparable to comparator product. Supporting data is not submitted, only summary sheets are submitted.
2.	3.2.P.5	It is not mentioned which dissolution test of USP will be used for your applied product. (test 1 or test 2 or test 3…. or test 10)	The firm has submitted that USP Test 2 will be used.
3.	3.2.P.5.2	In analytical procedures Dissolution is not mentioned. Clarify.	The firm has stated that it was a typographic mistake.
4.	3.2.P.5.4	In batch analysis, results of dissolution are provided at 8h time point only. Why sampling intervals as per USP are not followed?	The firm has stated that it was a typographic mistake and they have followed USP test 2 for their product.
5.	3.2.P.8	In chromatograms provided, sample name in all is "UNKNOWN001" it is not possible to identify which chromatogram is of RS and which is of drug product. Further in every chromatogram there are 2 to 3 major peaks. Which one is of the drug substance? Justify. In calculations values are mentioned around 0.9 under heading AUC, how does this value correspond to the area of curve in each chromatogram? If test is done on UV, then why pharmacopoeial method is not followed for test and analysis? (value of 0.9 corresponds to UV absorption)	• The firm has stated that sample name UNKNOWN001 is by default in system and cannot be changed. In sample description details of sample are given, the firm has submitted a copy of chromatogram with description Tamsulosin HCl 0.4mg capsule std 1 0 month. It has 2 major peaks of almost equal height even though chromatogram appears of std. The peak marked as of drug substance has less area than preceding peak. • Justification for peaks, firm has stated that peak of interest is recognized by considering retention time. • Retention time is determined by comparison for peaks obtained of working standard and also peak having maximum AUC, rest of the peaks are minor and ignored. • Calculations 0.9 show ratio between peaks of API and internal standard. • Test done on HPLC not on UV.

Decision of 331st meeting: Registration Board deferred the case for submission of clarification regarding unidentified peak in submitted chromatograms of assay having area more than the peak identified as drug substance.
Firm's reposne: Each chromatogram will have two major peaks as per USP method wherein each peak is of the Tamsulosin.
Decision: The board after detail delebration and keeping in view the reply submitted by the firm, deferred for submission of clarification in detail and also for the submission of complete analytical record for identification of the peaks exhibited in chromatograms of Assay analysis to be reviewed by the board.

68.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin-A 5/40 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate…….5mg Telmisartan……..40mg
	Diary No. Date of R & I & fee	Dy.No 29718; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as bilayered
	Me-too status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma (Reg.# 066943)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter. Manufacturing facility needs to be confirmed. The official monograph for the applied formulation is available in USP.
	Previous decision	Deferred in 293rd DRB meeting for the following: Evidence of purchase of required manufacturing equipment i.e. tablet bi- layered machine as reference product is a bi- layer tablet.
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Amlodipine as Besylate ……. 5mg** **Telmisartan …….. 40mg**	

	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
69.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- A 5/80 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate…….5mg Telmisartan……..80mg
	Diary No. Date of R & I & fee	Dy.No.29719; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Reg.# 066944)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • Manufacturing facility needs to be confirmed. • The official monograph for the applied formulation is available in USP. • On Form- 5, another strength 40mg & 10mg is mentioned.
	Previous decision	• Deferred in 293rd DRB meeting for the following: Evidence of purchase of required manufacturing equipment i.e. tablet bi- layered machine as reference product is a bilayer tablet. • On Form- 5, another strength 40mg & 10mg is mentioned while applied strength is 5mg/ 80 mg.
	Evaluation by PEC- XIII	• Firm has corrected the applied strength as 5mg/ 80 mg on Form- 5. • Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Amlodipine as Besylate ……. 5mg** **Telmisartan …….. 80mg**	

	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
70.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin-A 10/40 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate……...10mg Telmisartan……..40mg
	Diary No. Date of R & I & fee	Dy.No 29720; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 10mg + 40mg tablet of M/s Getz Pharma (Reg.# 066945)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter. Manufacturing facility needs to be confirmed. The official monograph for the applied formulation is available in USP. On Form- 5, another strength 40mg & 5mg is mentioned.
	Previous decision	Deferred in 293rd DRB meeting for the following: Evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet. On Form- 5, another strength 40mg & 5mg is mentioned while applied strength is 10mg/ 40 mg.
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • Firm has corrected the applied strength as 10mg/ 40 mg on Form- 5. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Amlodipine as Besylate ……. 10mg** **Telmisartan …….. 40mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
71.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Telmisin-A 10/80 mg tablet

	Composition	Each tablet contains: Amlodipine as Besylate……...10mg Telmisartan……..80mg
	Diary No. Date of R & I & fee	Dy.No.29721 ; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 10mg + 80mg tablet of M/s Getz Pharma (Reg.# 067472)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • Manufacturing facility needs to be confirmed. • Revise label claim as bi-layered. • The official monograph for the applied formulation is available in USP. • On Form- 5, another strength 40mg & 5mg is mentioned.
	Previous decision	Deferred in 293rd DRB meeting for the following: • Evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet. • On Form- 5, another strength 40mg & 5mg is mentioned while applied strength is 10mg/ 80 mg.
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • Firm has corrected the applied strength as 10mg/ 80 mg on Form- 5. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Amlodipine as Besylate ……. 10mg** **Telmisartan ……... 80mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
72.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- D 40/12.5 mg Tablet
	Composition	Each tablet contains: Telmisartan…….40mg

		Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy.No.29722; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Telsarta- D 40/12.5 tablet of M/s Pharm Evo (Reg. # 061915)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter. The official monograph for the applied formulation is available in USP. Manufacturing facility needs to be confirmed. Revise label claim as bi-layered.
	Previous decision	Deferred in 293rd DRB meeting for evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet.
	Evaluation by PEC- XIII	Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. But firm has not revised the master formulation as bi- layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Telmisartan…….40mg** **Hydrochlorothiazide…….12.5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
73.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- D 80/12.5 mg Tablet
	Composition	Each tablet contains: Telmisartan……..80mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy.No.29723; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Telsarta- D 80/12.5 tablet of M/s Pharm Evo (Reg. # 061914)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.

	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • The official monograph for the applied formulation is available in USP. • Manufacturing facility needs to be confirmed. • Revise label claim as bi-layered.
	Previous decision	Deferred in 293rd DRB meeting for evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision of 296th meeting: Deferred for following reasons: • Revision of formulation as per reference product i.e bi- layered tablet. • Submission of requisite fees for revision of formulation. • Submission of IQ, OQ and PQ documents.	
	Firm's response: Firm has submitted following: • IQ, OQ & PQ Report of ZP-33 Rotary Tablet Press Machine (Bi- layered) manufactured by Munawat Bhatti Engineering works.	
	Decision: Approved with USP specifications as per following label claim: **Each uncoated bilayer tablet contains:** **Telmisartan……..80mg** **Hydrochlorothiazide…….12.5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim to bi-layer tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

Case no. 02: Contract manufacturing applications applied on Form-5F

74.	Name, address of Applicant / Marketing Authorization Holder	**M/s Regal Pharmaceuticals** **Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued on 24-05-2021 based on the inspection dated 30-04-2021. The certificate is valid till 29-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 26-09-2019 specifying grant of dry powder injection (carbapenem) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9203 dated 05-04-2023
	Details of fee submitted	Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Mepen 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS- 4, National Industrial Zone, Rawat, Islamabad, Pakistan has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Manufacturer firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Brand Name: **DEWNEM Injection 500mg**	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
75.	Name, address of Applicant / Marketing Authorization Holder	**M/s Regal Pharmaceuticals** **Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued on 24-05-2021 based on the inspection dated 30-04-2021. The certificate is valid till 29-04-2023.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 26-09-2019 specifying grant of dry powder injection (carbapenem) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9204 dated 05-04-2023
	Details of fee submitted	Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Mepen 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS- 4, National Industrial Zone, Rawat, Islamabad, Pakistan has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Manufacturer firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Brand Name: DEWNEM Injection 1gm	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
76	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories Pvt Ltd.** **10 km, Faisalabad Road, Bikhi, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd.

		17/24, Korangi Industrial Area, Karachi, Pakistan
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate issued based on inspection dated 19-09-2020. The GMP certificate specifies Small Volume Lyophilized Injectable Section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued based on inspection dated 19-09-2020. The GMP certificate specifies Small Volume Lyophilized Injectable Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 8953 dated 03-04-2023 Rs.75,000/- dated 03-03-2023
	The proposed proprietary name / brand name	**Gramotive 4.5 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg of Colistin Base…4.5 MIU
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nabiqasim Industries Pvt Ltd.17/24, Korangi Industrial Area, Karachi, Pakistan has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
Manufacturer firm	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
Brand Name	NOGOTEX Injection 4.5MIU

Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

76.	Name, address of Applicant / Marketing Authorization Holder	**M/s Swiss Pharmaceuticals Pvt Ltd.** **A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	GMP certificate issued on 13-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 23-07-2012 which specifies Lyophilized vials (General) for M/s Bio-Labs Pharma
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 10004 dated 13-04-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**TGX 50mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline (Lyophillized Powder)…50mg
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Tigewel Injection of M/s Welwrd Pharma (Reg.# 082530)
	Name and address of API manufacturer.	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 330th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan Manufacturer firm: M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Uswatig 50mg injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	

77.	Name, address of Applicant / Marketing Authorization Holder	**M/s Rotex Pharma Pvt Ltd.** **Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Infusion section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 8947 dated 03-04-2023 Rs.75,000/- dated 17-03-2023
	The proposed proprietary name / brand name	**Nezo 2mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains Linezolid…2mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Atibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	300ml; As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Nezkil Infusion by Continental pharma
	Name and address of API manufacturer.	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.

Evaluation by PEC:

The applied product to be manufactured by M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	LINZOGEN 600mg/300ml Solution for Infusion

Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

78.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmevo Private Limited.** **Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	Copy of GMP certificate No. 3-16/2018-Addl. Dir (QA&LT-I)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad in favour of M/s Global Pharmaceuticals is provided.
	Evidence of approval of manufacturing facility	Copy of GMP certificate mentioning Capsule general and softgel capsule general sections is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12729 dated 23-05-2023 Rs.75,000/- dated 09-12-2022
	The proposed proprietary name / brand name	**Uritreat-DU 0.5mg/0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin Capsule Contains: Soft Gelatin Capsule of Dutasteride…0.5mg Tamsulosin Hcl as Modified Release Pellets 0.2%...0.4mg
	Pharmaceutical form of applied drug	Off white spherical pellets filled in empty HDSC with off white softgel capsule containing clear colourless translucent oily solution
	Pharmacotherapeutic Group of (API)	DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC Code: G04CA52
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Max flow D Capsule Reg. No. 091571 M/s CCL Pharmaceuticals.
	Name and address of API manufacturer.	Tamsulosin HCl 0.2% SR pellets M/s Vision Pharmaceuticals (Pvt.) ltd. Plot No. 22- 23, Industrial Triangle, Kahuta Road, Islamabad. **Dutasteride** M/s Stermone Chemicals (Pvt.) ltd. Survey No 36, Golana Road, PaldiSokhada, Tal-Khambhat, Dist. Anand, Gujrat India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 333rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58- A2, Korangi Creek Industrial Park (KCIP) Karachi. Manufacturer firm: M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204- 205, Industrial Triangle, Kahuta road Islamabad. Brand Name: TAMCURE-D Capsule	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
79.	Name, address of Applicant / Marketing Authorization Holder	**M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Infusion section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 18241 dated 19-07-2023 Rs.75,000/- dated 28-03-2023
	The proposed proprietary name / brand name	**Dyo-D 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Cholecalciferol…5mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Vitamin D3
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	ASNM France approved
	For generic drugs (me-too status)	ED3 Injection by GT Pharma
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India.
	Evaluation by PEC:	

<table>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s GT Pharma (Pvt) Ltd. 713 Sundar Industrial Estate Lahore. have already been approved by Registration Board in its 333rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table><tr><td>Applicant firm</td><td>M/s World Biz Pharmaceuticals Company (Pvt) Ltd. Plot No. 340, Multan Industrial Estate, Multan</td></tr><tr><td>Manufacturer firm</td><td>M/s GT Pharma (Pvt) Ltd. 713 Sundar Industrial Estate Lahore.</td></tr><tr><td>Brand Name</td><td>UP-D3 Injection 5mg/1ml</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>80.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Rotex Pharma Pvt Ltd.
Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Biogen Life Sciences.
8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Infusion section (General).</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 8948 dated 03-04-2023 Rs.75,000/- dated 17-03-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Curemox 400mg/250ml Infusion</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Moxifloxacin HCl…400mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Liquid injection</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Fluoroquinolone antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Avelox 400 mg/250 ml solution for infusion (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Avelox Injection by Bayer</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Shree Je Laboatory Pvt. Ltd. C-24 & 25 RIICO Industrial Area, Sotanala, Behror, District Alwar, Rajasthan India.</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	The applied product to be manufactured by M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi have already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: MOXIGEN 400mg/250ml Solution for Infusion	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
81.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone,Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020 declares availability of sachet general setion.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 18910 dated 27-07-2023 Rs.75,000/- dated 19-07-2023
	The proposed proprietary name / brand name	**Highzole-Insta 20/1680 mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole…20mg Sodium Bicarbonate…1680mg
	Pharmaceutical form of applied drug	Powder for oral suspension sachet
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Mep-Insta Sachet 40mg/1680mg of M/s Bio-Mark Pharmaceuticals
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited. Regd. Office & factory: Aroor Village, Sadasivpet

		Mandal, Sangareddy Dist. Telangana **Sodium Bicarbonate:** M/s TATA Chemicals Europe Ltd., Mond House, Winnington Lane, Northwich Cheshire, CW84DT,
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore have already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s CCL Pharmaceuticals (Pvt.) Ltd. Plot No 65-Quaid-e-Azam Industrial Estate Kot lakhpat, Lahore. Manufacturer firm: M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore Brand Name: Shalay 40mg/1680mg Sachet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
82.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore
	GMP status of the manufacturer	cGMP Certificate valid till 29th November 2024
	Evidence of approval of manufacturing facility	Copy of approved sections by Central Licensing Board of M/s CSH Pharmaceuticals (Pvt) Ltd. 32-Km Ferozepur Road Lahore (DML #000737) confirming "Tablet (Penicillin)", "Capsule (Penicillin)" and Dry Powder Suspension (Penicillin)" sections (Confirmed from letter dated 17-02-2023)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16718 dated 05-07-2023 Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Oxiclavo 156.25mg Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…125mg Potassium Clavulanate Eq. to Clavulanic Acid…31.25mg
	Pharmaceutical form of applied drug	Oral powder for suspension

	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Augmentin ® of M/s GSK
	Name and address of API manufacturer.	Amoxicillin Trihydrate Compacted M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. Potassium Clavulanate: Avicel (1:1) M/s Shangdong new time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian County, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Fortecin DS Suspension 156.25 mg/5ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
83.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore
	GMP status of the manufacturer	cGMP Certificate valid till 29th November 2024
	Evidence of approval of manufacturing facility	Copy of approved sections by Central Licensing Board of M/s CSH Pharmaceuticals (Pvt) Ltd. 32-Km Ferozepur Road Lahore (DML #000737) confirming "Tablet (Penicillin)", "Capsule (Penicillin)" and Dry Powder Suspension (Penicillin)" sections (Confirmed from letter dated 17-02-2023)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & Details of fee submitted	Dy.No 16721 dated 05-07-2023 Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Oxiclavo DS 312.50mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…250mg Potassium Clavulanate Eq. to Clavulanic Acid…62.50mg
	Pharmaceutical form of applied drug	Oral powder for suspension
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Augmentin ® of M/s GSK
	Name and address of API manufacturer.	Amoxicillin Trihydrate Compacted M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. Potassium Clavulanate: Avicel (1:1) M/s Shangdong new time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian County, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Fortecin DS Suspension 312.50 mg/5ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
84.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore
	GMP status of the manufacturer	cGMP Certificate valid till 29th November 2024
	Evidence of approval of manufacturing facility	Copy of approved sections by Central Licensing Board of M/s CSH Pharmaceuticals (Pvt) Ltd. 32-Km Ferozepur Road Lahore (DML #000737) confirming "Tablet (Penicillin)", "Capsule

		(Penicillin)" and Dry Powder Suspension (Penicillin)" sections (Confirmed from letter dated 17-02-2023)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16719 dated 05-07-2023 Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Oxiclavo DS 625mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…500mg Potassium Clavulanate Eq. to Clavulanic Acid…125mg
	Pharmaceutical form of applied drug	Oral Tablet Dosage form
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Augmentin ® of M/s GSK
	Name and address of API manufacturer.	Amoxicillin Trihydrate Compacted M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. Potassium Clavulanate: Avicel (1:1) M/s Shangdong new time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian County, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi
Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	Tablet Fortecin 625 mg

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

85.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore
	GMP status of the manufacturer	cGMP Certificate valid till 29th November 2024
	Evidence of approval of manufacturing facility	Copy of approved sections by Central Licensing Board of M/s CSH Pharmaceuticals (Pvt) Ltd. 32-Km Ferozepur Road Lahore (DML #000737) confirming "Tablet (Penicillin)", "Capsule (Penicillin)" and Dry Powder Suspension (Penicillin)" sections (Confirmed from letter dated 17-02-2023)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16717 dated 05-07-2023 Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Oxiclavo Forte 1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…875mg Potassium Clavulanate Eq. to Clavulanic Acid…125mg
	Pharmaceutical form of applied drug	Oral Tablet Dosage form
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Augmentin ® of M/s GSK
	Name and address of API manufacturer.	Amoxicillin Trihydrate Compacted M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. Potassium Clavulanate: Avicel (1:1) M/s Shangdong new time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian County, Shandong Province, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Tablet Fortecin 1000 mg	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
86.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore
	GMP status of the manufacturer	cGMP Certificate valid till 29th November 2024
	Evidence of approval of manufacturing facility	Copy of approved sections by Central Licensing Board of M/s CSH Pharmaceuticals (Pvt) Ltd. 32-Km Ferozepur Road Lahore (DML #000737) confirming "Tablet (Penicillin)", "Capsule (Penicillin)" and Dry Powder Suspension (Penicillin)" sections (Confirmed from letter dated 17-02-2023)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16720 dated 05-07-2023 Rs.75,000/- dated 27-03-2023
	The proposed proprietary name / brand name	**Oxiclavo 375mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Amoxicillin Trihydrate Eq. to Amoxicillin ….. 250mg Potassium Clavulanate Eq. to Clavulanic Acid ….. 125mg
	Pharmaceutical form of applied drug	Oral Tablet Dosage form
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Augmentin ® of M/s GSK

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Amoxicillin Trihydrate Compacted
M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road,
Lahore.
Potassium Clavulanate: Avicel (1:1)
M/s Shangdong new time Pharmaceutical Co. Ltd.
No. 01, North Outer Ring Road, Feixian County,
Shandong Province, China.</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table><tr><td>Applicant firm</td><td>M/s The Searle Company Limited (DML # 000016)
F-319, S.I.T.E. Karachi</td></tr><tr><td>Manufacturer firm</td><td>M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr><tr><td>Brand Name</td><td>Tablet Fortecin 375 mg</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>87.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Siam Pharmaceuticals.
217, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Capsule Cephalosporin section</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 18434 dated 21-07-2023 Rs.75,000/- dated 23-06-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Sixime 200mg Capsule</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Capsule Contains:
Cefixime Trihydrate Eq. to Cefixime…200mg</td></tr>
</table>

	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Saf-Xime 200mg/5ml Dry suspension	
	Decision: Approved as per manufacturer's specifications notified vide Notification no. F.14-1/2022-PEC dated 14-03-2022. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
88.	Name, address of Applicant / Marketing Authorization Holder	**M/s Siam Pharmaceuticals.** **217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry powder suspension Cephalosporin section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 18433 dated 21-07-2023 Rs.75,000/- dated 23-06-2023

	The proposed proprietary name / brand name	**Sixime 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cefixime Trihydrate Eq. to Cefixime…200mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cefixima Normon 200 Mg Hard Capsules EFG Approved by AEMPS of Spain. Approved)
	For generic drugs (me-too status)	Secure 200mg capsule of Wilshire
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	TRISPAN 200mg Capsule

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
89.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12217 dated 18-05-2023 Rs.75,000/- dated 13-04-2023
	The proposed proprietary name / brand name	**Tazocin 4.5gm Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…4000mg Tazobactam Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 4.5gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
90.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12215 dated 18-05-2023 Rs.75,000/- dated 13-04-2023

	The proposed proprietary name / brand name	**Tazocin 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…4000mg Tazobactam Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 4.5gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
91.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & Details of fee submitted	Dy.No 12219 dated 18-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…4000mg Tazobactam Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 4.5gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
92.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 11798 dated 15-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…4000mg Tazobactam Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 4.5gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
93.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 11796 dated 15-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…4000mg Tazobactam Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 4.5gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
94.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12214 dated 18-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 2.25gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…2000mg Tazobactam Sodium…250mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 2.25gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
95.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 11795 dated 15-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 2.25gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…2000mg Tazobactam Sodium…250mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 2.25gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
96.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12216 dated 18-05-2023 Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Tazocin 2.25gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium…2000mg Tazobactam Sodium…250mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China Peviously Qilu Tianhe Pharmaceuticals co.,Ltd
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: TAZOCIN 2.25gm Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
97.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura

	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided tablet section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16623 dated 04-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Pantac 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pantoprazole Sodium Eq. to Pantoprazole……40mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	PROTIUM 40 mgTablets by by M/s Abbott Pharma (Pvt.) Ltd. Reg. No. 021039
	Name and address of API manufacturer.	M/s JPR Labs Private Limited Plot No.74/A, J.N. Pharma city, Thanam Village, Parawada Mandal, Visakhapatnam- 531019, Andra Pradesh, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: PANTO 40mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
98.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**

	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided tablet section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16622 dated 04-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Paintec 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Piroxicam Beta Cyclodextrin Eq. to Piroxicam…20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID (WHO ATC Code: M02AC01)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Achway Tablets of M/s Getz Pharma (Reg.#047355)
	Name and address of API manufacturer.	M/s Nantong Jinghua Pharmaceutical Co., Ltd., No. 20, 3 Haibin Road, Yenhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: PIXIVAR 20mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	

99.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided tablet section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16630 dated 04-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Moxison 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Moxifloxacin Hcl Eq. to Moxifloxacin…400mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotic (ATC Code: J01MA14)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Moxiget 400mg Tablet of M/s Getz Pharma (Reg.#047117)
	Name and address of API manufacturer.	M/s SHREE JEE LABORATORY Pvt. Ltd. C-24 & 25, RIICO Indl. Area, Sotanala, Behror-301701, District. Alwar (Rajasthan.) India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Brand Name	MOXIVAR 400mg Tablet

	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
100.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided capsule section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16629 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Dexlin 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets Eq. to Dexlansoprazole…….60mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Razodex 60 mg Capsule of M/s GETZ Pharma (Reg # 086976)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Brand Name	DEXIRANT 60mg Capsules

	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
101.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided capsule section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16628 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Dexlin 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets Eq. to Dexlansoprazole…30mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Razodex 30 mg Capsule of M/s GETZ Pharma (Reg # 086976)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: DEXIRANT 30mg Capsules \	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
102.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided capsule section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16617 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Prelix 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Pregabalin…50mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Anticonvulsant (WHO ATC Code: N03AX16)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	ZEEGAP 50mg Capsule of M/s Hilton pharma
	Name and address of API manufacturer.	M/s Almelo (Pvt.) Ltd. Unit II, Survey no. 227, 228 & 136, 137 Shabashpally village, Shivampet Mandal Medak,

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: V-GAB 50mg Capsule	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
103.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided capsule section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16716 dated 05-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Esolip 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Esomeprazole Magnesium Trihydrate Enteric Coated Pellets Eq. to Esomeprazole…20mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor (A02BC05)
	Reference to Finished product specifications	USP specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Espra Capsule 20mg. Reg. No. 33097
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: ESOVAR 20mg Capsule	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
104.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided capsule section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16714 dated 05-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Esolip 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Esomeprazole Magnesium Trihydrate Enteric Coated Pellets Eq. to Esomeprazole…40mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor (A02BC05)
	Reference to Finished product specifications	USP specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Espra Capsule 40mg. Reg. No. 33051
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: ESOVAR 40mg Capsule	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
105.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone,Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	M/s Bio-Mark Pharmaceuticals was granted cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	The manufacturer (M/s Bio-Mark Pharma) has provided Oral Syrup (General) section confirmed from letter no.F.1-29/2011- Lic.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 18909 dated 27-07-2023 Rs.75,000/- dated 19-07-2023
	The proposed proprietary name / brand name	**Curetadine 0.5mg/ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Desloratadine…0.5mg
	Pharmaceutical form of applied drug	Oral Liquid
	Pharmacotherapeutic Group of (API)	Antihistamines -H_1 antagonists (R06AX27)
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by AEMPS of Spain
	For generic drugs (me-too status)	Desora 0.5mg/ml Syrup of M/s Continental Pharma (Reg#055192)
	Name and address of API manufacturer.	M/s Morepen Laboratories Ltd. Village-Masulkhana, Parwanoo, Distt. Solan India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore Brand Name: VARIDINE SYRUP	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
106.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sapient Pharma** **123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	M/s Bio-Mark Pharmaceuticals was granted cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	The manufacturer (M/s Bio-Mark Pharma) has provided Oral Syrup (General) section confirmed from letter no.F.1-29/2011- Lic.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 18912 dated 27-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Deslor Syrup 0.5mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Desloratadine…0.5mg
	Pharmaceutical form of applied drug	Oral Liquid
	Pharmacotherapeutic Group of (API)	Antihistamines -H_1 antagonists (R06AX27)
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by AEMPS of Spain
	For generic drugs (me-too status)	Desora 0.5mg/ml Syrup of M/s Continental Pharma (Reg#055192)
	Name and address of API manufacturer.	M/s Morepen Laboratories Ltd. Village-Masulkhana, Parwanoo, Distt. Solan India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore Brand Name: VARIDINE SYRUP	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
107.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Tablet section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16620 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Cipflox 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ciprofloxacin HCl Eq. to Ciprofloxacin …… 500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Immediate release tablet
	Reference to Finished product specifications	Quinolones (WHO ATC Code: S02AA15)
	Proposed Pack size & Unit price	USP specification
	The status in reference regulatory authorities	CIPRO 500mg Tablet of Bayer healthcare (USFDA Approved)
	For generic drugs (me-too status)	Ciproxin 500mg Tablet of Bayer pakistan
	Name and address of API manufacturer.	M/s Pharmagen Ltd, Kot Nabi Bakhsh Wala, 34-Km, Ferozpur Road, Lahore
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: CIPROVAR 500mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
108.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Tablet section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16619 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Cipflox 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ciprofloxacin HCl Eq. to Ciprofloxacin …… 250mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Immediate release tablet
	Reference to Finished product specifications	Quinolones (WHO ATC Code: S02AA15)
	Proposed Pack size & Unit price	USP specification
	The status in reference regulatory authorities	CIPRO 250mg Tablet of Bayer healthcare (USFDA Approved)
	For generic drugs (me-too status)	Ciproxin 250mg Tablet of Bayer pakistan
	Name and address of API manufacturer.	M/s Pharmagen Ltd, Kot Nabi Bakhsh Wala, 34-Km, Ferozpur Road, Lahore

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Manufacturer firm: M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura Brand Name: CIPROVAR 250mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
109.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17611 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Vonocare 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved

	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd. Block No. 82/B, ECP Road, AT & Post. Karakhadi, Tal-Padra Karakhadi-391 450 District Vadodara Gujrat State India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Manufacturer firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Brand Name — Vonozen 10mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
110.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17612 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Vonocare 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification

	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd. Block No. 82/B, ECP Road, AT & Post. Karakhadi, Tal-Padra Karakhadi-391 450 District Vadodara Gujrat State India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Manufacturer firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Brand Name — Vonozen 20mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
111.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17611 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Vonocare 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg

	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd. Block No. 82/B, ECP Road, AT & Post. Karakhadi, Tal-Padra Karakhadi-391 450 District Vadodara Gujrat State India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Manufacturer firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Brand Name — Vonozen 10mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
112.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17605 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Myco 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….1gm

	Pharmaceutical form of applied drug	Dry Powder injection
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 1gm Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Myocin 1gm Dry Powder vial I.V	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
113.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17604 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Myco 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride equivalent to Vancomycin …….500mg (as lyophilized powder for injection)

	Pharmaceutical form of applied drug	Dry Powder injection
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 500mg Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Myocin 500mg Dry Powder vial I.V	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
114.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17788 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Ticrole 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Ttablet Contains: Ticagrelor…90mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size & Unit price	As per SRO

	The status in reference regulatory authorities	Brilinta 90 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 90mg, PharmEvo (Pvt.) Ltd.,
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Ticlor 90mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
115.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17787 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Ticrole 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Ttablet Contains: Ticagrelor…60mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Brilinta 60 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 60mg, PharmEvo (Pvt.) Ltd., Reg. No.093105.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Rudong Coastal

		Economic Development Zone, Nantong, Jiangsu Province 226407, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Ticlor 90mg Tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
116.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17814 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Tenofa 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
117.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17799 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tenfold 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
118.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17741 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Tenfova 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
119.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17807 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Typend 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	

<table>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table><tr><td>Applicant firm</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr><tr><td>Manufacturer firm</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr><tr><td>Brand Name</td><td>Tapentawel 75mg tablet</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>120.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Weather Folds Pharmaceuticals.
Plot # 69, Phase-II, Industrial Estate, Hattar</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17797 dated 14-07-2023 Rs.75,000/- dated 12-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Tepind 75mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Film Coated Tablet Contains:
Tapentadol as HCl……75mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Film coated tablets.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Analgesic, opioids</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Product Complies Innovator’s Specs</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>USFDA Approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Precise Chemipharma Pvt Limited, C384, TTC
Industrial area, MIDC, Pawne village, Nawi Mumbai,
India</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
121.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17816 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Tepinda 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
122.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17716 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Tapent 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
123.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17694 dated 14-07-2023, Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tenpand 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	

<table>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table><tr><td>Applicant firm</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr><tr><td>Manufacturer firm</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr><tr><td>Brand Name</td><td>Tapentawel 75mg tablet</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>124.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Welwrd Pharmaceuticals.
Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17697 dated 14-07-2023 Rs.75,000/- dated 13-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Typint 75mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Film Coated Tablet Contains:
Tapentadol as HCl……75mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Film coated tablets.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Analgesic, opioids</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Product Complies Innovator’s Specs</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>USFDA Approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Precise Chemipharma Pvt Limited, C384, TTC
Industrial area, MIDC, Pawne village, Nawi Mumbai,
India</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
125.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17810 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Resko 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
126.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17809 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Resko 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
127.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17803 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Racefo 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
128.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17802 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Racefo 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
129.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17828 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Riseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
130.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17827 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Riseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
131.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17818 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Raceba 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
132.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17817 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Raceba 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
133.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17721 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
134.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
135.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwrd Pharmaceuticals.** **Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17700 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raceka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
136.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwrd Pharmaceuticals.** **Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17700 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raceka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
137.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17704 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Racode 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The	

	details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
138.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17703 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Racode 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
139.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Evidence of approval of manufacturing facility	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17921 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Tazopin 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang RdDongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Fleming Pharmaceutical 23- Km Lahore- Sheikhupura Road, Lahore.has already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm — M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Manufacturer firm — M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Brand Name — Fletazo Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
140.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Evidence of approval of manufacturing facility	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 17920 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Tazopin 2.25gm Injection**
	trength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang RdDongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Fleming Pharmaceutical 23- Km Lahore- Sheikhupura Road, Lahore.has already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm — M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Manufacturer firm — M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Brand Name — Fletazo Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
141.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section.

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17710 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazip 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore has already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila Brand Name: ARDCIL Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
142.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig,

		Multan Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17709 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazip 2.25gm Injection**
	trength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore has already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: ARDCIL Injection 2.25g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
143.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection dated 22-09-2020 for M/s Stallion Pharma specifying dry powder injection Vial (Penicillin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17577 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazocal 4.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Shandong (Previously Qilu) Anxin Pharmaceutical Co., Ltd. 10678 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan has already been approved by Registration Board in its 308th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi Manufacturer firm: M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan Brand Name: PITZO Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
144.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection dated 22-09-2020 for M/s Stallion Pharma specifying dry powder injection Vial (Penicillin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17576 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 22-06-2022
	The proposed proprietary name / brand name	**Tazocal 2.25gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g

	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Shandong (Previously Qilu) Anxin Pharmaceutical Co., Ltd. 10678 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan has already been approved by Registration Board in its 308th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm: M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi Manufacturer firm: M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan Brand Name: PITZO Injection 2.25 Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
145.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16624 dated 04-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Pantac 40mg IV Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Lyophillized Vial Contains: Pantoprazole Sodium Eq. to Pantoprazole…….40mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Pantoprazole sodium 40mg IV Injection of M/s Sandoz Inc (USFDA approved)
	For generic drugs (me-too status)	NEEGE 40mg Injection of M/s Sami Pharma (Reg # 057832)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm — M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name — PANTO 40mg IV Injection The composition of applied formulation shall not mention "Lyophilized vial".	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
146.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nicholas Pharmaceuticals.** **Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued to the firm on 02-03-2021 based on inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm on 02-03-2021 based on inspection conducted on 02-03-2021 declares Tablet general section availability..
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17580 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Ondex 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……8mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47, D-48, D-49, D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru, Dist: Bengaluru Rural-561203 India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistanhas already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 322nd meeting are as follows: Applicant firm — M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan Manufacturer firm — M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan Brand Name — Calsetron 8mg tablet	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
147.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals:

		GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable ampoule Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17756 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia injection 8mg/4ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
148.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**

	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable ampoule Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17758 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan	

	Manufacturer firm Brand Name	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Stawia injection 4mg/2ml
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
149.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17759 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl dihydrate…4mg
	Pharmaceutical form of applied drug	Oral liquid
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar	

	Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia Syrup 4mg/5ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
150.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Tablet general section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17783 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……8mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.

	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia 8mg tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
151.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Tablet general section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17782 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……4mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 4mg tablet by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia 4mg tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
152.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable ampoule Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17780 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 8mg/4ml Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia injection 8mg/4ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
153.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable ampoule Section
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17780 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia injection 4mg/2ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
154.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract

		giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17779 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl dihydrate…4mg
	Pharmaceutical form of applied drug	Oral liquid
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia Syrup 4mg/5ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
155.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527,

		Sundar Industrial Estate,Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 12-06-2017 specifying Oral syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17740 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Ondcare 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl dihydrate…4mg
	Pharmaceutical form of applied drug	Clear to straw coloured syrup filled in amber coloured PET bottle
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK
	Name and address of API manufacturer.	Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSS DC Industrial Estate, Doddaballapur, Banglore, Karnata India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm — M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot Manufacturer firm — M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore Brand Name — Aptron Syrup 4mg/5ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	

156.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone,Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 12-06-2017 specifying Oral syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18911 dated 27-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Hidaesetron 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl dihydrate…4mg
	Pharmaceutical form of applied drug	Clear to straw coloured syrup filled in amber coloured PET bottle
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK
	Name and address of API manufacturer.	Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSS DC Industrial Estate, Doddaballapur, Banglore, Karnata India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm — M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot Manufacturer firm — M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore Brand Name — Aptron Syrup 4mg/5ml	
	Decision: Approved.	

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
157.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**M/s English Pharmaceuticals:** Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Evidence of approval of manufacturing facility	**M/s English Pharmaceuticals:** The firm has provided Dry powder injection vials (General) approval.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17916 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Oray 40mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg Powder for Solution for Infusion (MHRA)
	For generic drugs (me-too status)	Risek 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore. Manufacturer firm — M/s English Pharmaceuticals. Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name — Nilcid 40mg Injection	
	Decision: Approved.	

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
158.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16625 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Omelip 40gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg IV Injection of M/s Lek Pharmaceuticals (MHRA approved)
	For generic drugs (me-too status)	Risek 40mg IV powder for solution of M/s GETZ Pharma (Reg # 024170)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Varizole 40mg Injection	

	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
159.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**M/s English Pharmaceuticals:** Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Evidence of approval of manufacturing facility	**M/s English Pharmaceuticals:** The firm has provided Dry powder injection vials (General) approval.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17755 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sar-Omep 40mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg Powder for Solution for Infusion (MHRA)
	For generic drugs (me-too status)	Risek 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore. Manufacturer firm — M/s English Pharmaceuticals. Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name — Nilcid 40mg Injection	

	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
160.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17579 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Merop 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 500 mg Injection IV**	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
161.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17578dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Merop 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 1gm Injection IV**	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
162.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17811 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Nopem 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)

	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
163.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 17812 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Nopem 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
164.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021

	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17825 dated 14-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Myrona 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
165.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17826 dated 14-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Myrona1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved.	

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
166.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17713 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 10-07-2023
	The proposed proprietary name / brand name	**Mopina 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
167.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17714 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 10-07-2023
	The proposed proprietary name / brand name	**Mopina 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)

	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
168.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17701 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 07-07-2023
	The proposed proprietary name / brand name	**Meprox 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials

	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
169.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17702 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 07-07-2023

	The proposed proprietary name / brand name	**Meprox 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
170.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17808 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Jestro 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet

	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Brand Name: Mygest 160mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
171.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17815 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Myggo 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.</td></tr>
<tr><td>Brand Name</td><td>Mygest 160mg Tablet</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>172.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Welwrd Pharmaceuticals.
Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17696 dated 14-07-2023 Rs.75,000/- dated 13-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Majest 160mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each tablet contains:
Megestrol Acetate …….160mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Tablet</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Hormone related agent. (L02AB01)</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>MHRA Approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Brand Name: Mygest 160mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
173.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17707 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Mygeso 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Brand Name: Mygest 160mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
174.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17693 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Mestrol 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan. Brand Name: Mygest 160mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
175.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17784 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Lefaa 600mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lefamulin as Acetate……..600mg
	Pharmaceutical form of applied drug	Antibacterial
	Pharmacotherapeutic Group of (API)	Immediate release film coated tablet
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Xenelta 600mg tablet, USFDA Approved.
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Kaifeng Pharmaceutical (Group) Company Limited, No. 1, Yunan street, Kaifeng Henan, Province, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: **Lefazon tablet 600mg**	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
176.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gelatin Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17752 dated 14-07-2023 Rs.75,000/- dated 07-07-2023
	The proposed proprietary name / brand name	**Isovin 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Yellow color soft gel capsule containing yellow color liquid
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Biogen Life Scie nces8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIOTAN 20mg Capsule	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
177.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17801 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Imastin 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate…500mg Cilastatin as Sodium…500mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: Nemcil 500mg/5000mg injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
178.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17800 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Imastin 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……250mg Cilastatin (as sodium)……250mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: Nemcil 250mg/250mg injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
179.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17712 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Imsetin 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate…500mg Cilastatin as Sodium…500mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: Nemcil 500mg/5000mg injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
180.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17711 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Imsetin 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……250mg Cilastatin (as sodium)……250mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: Nemcil 250mg/250mg injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
181.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019, declares availability of Liquid injectable vial & ampoule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17757 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarferric 500mg/10ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Iron as Ferric Carboxymaltose…50mg/ml
	Pharmaceutical form of applied drug	IV Liquid injection
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Ferotox 50mg/ml Injection of M/s Wilshire Laboratories Reg.# 108356
	Name and address of API manufacturer.	M/s Nanjing Hancer Pharmaceutical Co., Ltd., China, No. 18 Hichang Road, Lishui Economi Technlogical Development one Jiangsu, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Aptcure Pvt Ltd. 8- Pharma City, 30 km Multan Road, Lahore Manufacturer firm: M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Greeninject 50mg/ml Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
182.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019, declares availability of Liquid injectable vial & ampoule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17708 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Haem 50mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Iron as Ferric Carboxymaltose…50mg/ml
	Pharmaceutical form of applied drug	IV Liquid injection
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Ferotox 50mg/ml Injection of M/s Wilshire Laboratories Reg.# 108356
	Name and address of API manufacturer.	M/s Nanjing Hancer Pharmaceutical Co., Ltd., China, No. 18 Hichang Road, Lishui Economi Technlogical Development one Jiangsu, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Aptcure Pvt Ltd. 8- Pharma City, 30 km Multan Road, Lahore Manufacturer firm: M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Greeninject 50mg/ml Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.Decision:**	
183.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwrd Pharmaceuticals.** **Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17698 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Ezonpp 375/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …. 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338

	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
184.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17795 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Eznop 500/20 mg DR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …. 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors

		Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
185.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17794 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Eznop 375/20 mg DR Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
186.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17830 dated 14-07-2023 Rs.75,000/
	The proposed proprietary name / brand name	**Esonap 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.Decision:**	
187.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar

		Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17829 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Esonap 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR ……. 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Brand Name	Esonyp 20/375mg DR Tablet

Decision: Approved.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
188.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17822 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esonepp 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …….. 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
189.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17821 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esonepp 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338

	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
190.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Zonepp 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors

		Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
191.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Zonepp 20/375 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
192.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17706 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esopenn DR 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …….. 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
193.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals.

		Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17705 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esopenn DR 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …….. 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	

The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Brand Name	Esonyp 20/375mg DR Tablet

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
194.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17610 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esoncar DR 20/500 mg Table**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
195.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17609 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esoncar DR 20/375 mg Table**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338

	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
196.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17717 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Emzaa 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Erli tablet of M/s Pharm Evo
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **EMPAZIN 25MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
197.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17602 dated 13-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tavar 40mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Drotaverine Hcl Eq. to Drotaverine…40mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antispasmodic, Anticholinergic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved in 3 European countries (Hungary, Romania, Bulgaria)
	For generic drugs (me-too status)	No-spa 40mg/2ml by M/s Snofi pharma
	Name and address of API manufacturer.	M/s R.A Chem Pharma, Ltd India.
	Evaluation by PEC:	

<table>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table><tr><td>Applicant firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr><tr><td>Manufacturer firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr><tr><td>Brand Name</td><td>Doviene 40mg/2ml injection</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>198.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Welwrd Pharmaceuticals.
Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17753 dated 14-07-2023 Rs.75,000/- dated 13-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Dapag 5mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Film Coated Tablet Contains:
Dapagliflozin as Propanediol Monohydrate…5mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Film coated tablets.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Anti-Diabetic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Product Complies Innovator’s Specs</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Forxiga Tablet , USFDA Approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
199.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17813 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Dappa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
200.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17798 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Deffa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
201.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17793 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Daglo 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
202.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17823 dated 14-07-2023 Rs.75,000/
	The proposed proprietary name / brand name	**Dapego 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
203.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17715 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Dypa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
204.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No. 17919 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Coliswim 150mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colizone 4.5MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>205.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>English pharmaceuticals: Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17918 dated 14-07-2023 Rs.75,000/-</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Coliswim 68mg Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
</table>

<table>
<tr><td></td><td>The status in reference regulatory authorities</td><td>COLOMYCIN 2 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Colistimethate injection 2 MIU by Mukhtar Enterprises</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colizone 2MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>206.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>English pharmaceuticals: Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No. 17917 dated 14-07-2023 Rs.75,000/-</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Coliswim 34mg Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity</td></tr>
</table>

	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: **M/s Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
207.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17772 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Colistat 150mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity

<table>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>COLOMYCIN 4.5 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>N/A</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td>Manufacturer firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colmate 4.5MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>208.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Caliph Pharmaceuticals Pvt Ltd.
Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s May & Baker (Pvt) Ltd.
45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17771 dated 14-07-2023 Rs.75,000/- dated 14-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Colistat 68mg Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity</td></tr>
</table>

	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	Colmate 2MIU Injection

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
209.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17770 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Colistat 34mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity

	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Colmate 1MIU Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
210.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17608 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 4.5 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity

	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Colmate 4.5MIU Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
211.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17607 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 2 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.

	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	Colmate 2MIU Injection

	Decision:	
212.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17606 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 1 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO

	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Colmate 1MIU Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
213.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17778 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 150mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.

	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 4.5MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
214.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17777 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 68mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains:

		Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 2MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
215.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & Details of fee submitted	Dy.No 17776 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 34mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: **M/s Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
216.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17724 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Cholisti 150mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 4.5MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
217.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022.

<table>
<tr><td></td><td></td><td>The certificate specifies dry powder injection general section..</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17722 dated 14-07-2023 Rs.75,000/- dated 12-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cholisti 68mg Powder for Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>COLOMYCIN 2 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Colistimethate injection 2 MIU by Mukhtar Enterprises</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colizone 2MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>218.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Bio Mark Pharmaceuticals.
Plot No. 527, Sundar Industrial Estate,Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>English pharmaceuticals: Firm has submitted copy of GMP certificate dated 17-</td></tr>
</table>

		08-2022. The certificate was issued based on the inspection dated 14-07-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection general section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17722 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Cholisti 34mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: **M/s Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
219.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore

	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17603 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Wincit 1gm/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule Contains: Citicoline Sodium as Citicoline …… 1gm
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Psychostimulant and nootropic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved b AIFA of Italy
	For generic drugs (me-too status)	Citolin innjection by M/s Global Pharma Reg. No.030541
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	C-Coline 1gm/4ml Injection

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
220.	Name, address of Applicant / Marketing Authorization Holder	**M/s Venus Pharma.** **23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.

	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17769 dated 14-07-2023 Rs.75,000/- dated 26-06-2023
	The proposed proprietary name / brand name	**Xinva 2gm IV Dry Powder For Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……2gm
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 2gm IV injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	

221.	Name, address of Applicant / Marketing Authorization Holder	**M/s Venus Pharma.** **23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17767 dated 14-07-2023 Rs.75,000/- dated 26-06-2023
	The proposed proprietary name / brand name	**Xinva 250mg IM Dry Powder For Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
Brand Name	Genxone 250mg IM injection

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
222.	Name, address of Applicant / Marketing Authorization Holder	**M/s Venus Pharma.** **23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17768 dated 14-07-2023 Rs.75,000/- dated 26-06-2023
	The proposed proprietary name / brand name	**Xinva 1gm IM Dry Powder For Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1gm
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

	Applicant firm	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.
	Manufacturer firm	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Brand Name	Genxone 1gm IM injection
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
223.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17748 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 5 IV injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
224.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17746 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1gm
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)

	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 1gm IV injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
225.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17745 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 1gm IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1gm
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.

	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 1gm IM injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
226.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17747 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 2gm IV Injection**
	Strength / concentration of drug of Active	Each vial contains:

	Pharmaceutical ingredient (API) per unit	Ceftriaxone (as sodium)……2gm
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 2gm IV injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
227.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17744 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 500mg IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 500mg IM injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
228.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17743 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 250mg IV injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
229.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17742 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Cuxone 250mg IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 250mg IM injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
230.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan

	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry Powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17751 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……200mg
	Pharmaceutical form of applied drug	Dry powder suspesnion
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Pdfim 100mg/5ml	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
231.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**

	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry Powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17749 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……100mg
	Pharmaceutical form of applied drug	Dry powder suspesnion
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 100mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 100mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm — M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name — Pdfim 100mg/5ml	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years.	

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
232.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals. 40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Capsule (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17751 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 400mg capsule by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Pdfim 400mg capsule	

	Decision: Approved as per manufacturer's specifications notified vide Notification no. F.14-1/2022-PEC dated 14-03-2022. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
233.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17786 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Bemzeox-E 180/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Bempedoic Acid…….180mg Ezetimibe……...10mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor Ezetimibe: adenosine triphosphate-citrate lyase (ACL) inhibitor, Cholesterol absorption inhibitor.
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nexilzet tablet approved by US FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Bempedoic Acid: Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND). Ezetimibe: Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Bempp-z 180/10mg tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
234.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17785 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Bemzeox 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic Acid…180mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nexlitol Tablets 180mg approved by US-FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Bempex Tablet 180mg	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
235.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17791 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar-C 40/12.5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Azilsartan Medoxomil as Potassium ..... 40mg Chlorthalidone …….. 12.5mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Azilsartan Medoxomil Potassium: Angiotensin II antagonist Chlorthalidone: Benzothiadiazine Diuretic
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	EDARBYCLOR Tablet 40mg/12.5mg approved by US-FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Azilsartan Medoxomil Potassium: CTX Life Sciences Pvt Ltd Block no: 251-252-Sachin-Magdalla Road

		GIDC Sachin, Surat-394 230 Gujrat India **Chlorthalidone**: Menadiaona S.L Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azila-C Tablet 40/12.5	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
236.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M/s Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17792 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar-C 40/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Azilsartan Medoxomil as Potassium ..... 40mg Chlorthalidone …….. 25mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Azilsartan Medoxomil Potassium: Angiotensin II antagonist Chlorthalidone: Benzothiadiazine Diuretic
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	EDARBYCLOR Tablet 40mg/25mg approved by US-FDA

	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Azilsartan Medoxomil Potassium: CTX Life Sciences Pvt Ltd Block no: 251-252-Sachin-Magdalla Road GIDC Sachin, Surat-394 230 Gujrat India **Chlorthalidone**: Menadiaona S.L Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azila-C Tablet 40/25	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
237.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17790 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved by US FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No: 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC Sachin, Surat-394 230 Gujarat, India

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azilsartan Medoxomil 80mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
238.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17789 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….40mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 40mg tablet approved by US FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No: 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC Sachin, Surat-394 230 Gujarat, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azilsartan Medoxomil 40mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
239.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17804 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Azzota 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….40mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 40mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 40MG TABLET	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
240.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17805 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Azzota 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 80MG TABLET	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
241.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17819 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Azzilta 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….40mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 40mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 40MG TABLET	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
242.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17820 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Azzilta 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 80MG TABLET	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
243.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17806 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Vospin 10/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer)……...…10mg Aspirin (as enteric coated inner core) ……..…..100mg
	Pharmaceutical form of applied drug	White to off-white color Aspirin round shape enteric coated tablet surrounded by film coated Vonoprazan tablets.
	Pharmacotherapeutic Group of (API)	Vonoprazan: Potassium-Competitive Acid Blocker Aspirin: Antithrombotic Agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO

<table>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Not available</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Vonoprazan:
Guangdong Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China
Aspirin
JQC (HUAYIN) Pharmaceutical Co, Ltd/ Yuquan Road, Huayin city, Shanxi province, P.R of China</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table>
<tr><td>Applicant firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan</td></tr>
<tr><td>Manufacturer firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan</td></tr>
<tr><td>Brand Name</td><td>Venospa 10/100mg Tablet</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>244.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17695 dated 14-07-2023 Rs.75,000/- dated 12-07-2023</td></tr>
</table>

	The proposed proprietary name / brand name	**Vono-AS 10/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer)……...…10mg Aspirin (as enteric coated inner core) ……..…..100mg
	Pharmaceutical form of applied drug	White to off-white color Aspirin round shape enteric coated tablet surrounded by film coated Vonoprazan tablets.
	Pharmacotherapeutic Group of (API)	Vonoprazan: Potassium-Competitive Acid Blocker Aspirin: Antithrombotic Agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Vonoprazan: Guangdong Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China Aspirin JQC (HUAYIN) Pharmaceutical Co, Ltd/ Yuquan Road, Huayin city, Shanxi province, P.R of China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan Brand Name: Venospa 10/100mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
245.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**M/s English Pharmaceuticals:** Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.

	Evidence of approval of manufacturing facility	**M/s English Pharmaceuticals:** The firm has provided Dry powder injection vials (General) approval.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17915 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Aldis 40mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Nexium 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Sterile India Pvt. Ltd Plot No.100, 118-G, Sector-56, Phase-IV, HSIIDC, Kundli District Sonepat, Haryana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore. Manufacturer firm — M/s English Pharmaceuticals. Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name — Epsol 40mg Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
246.	Name, address of Applicant / Marketing Authorization Holder	**M/s Aptcure Pvt Ltd** **8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.

	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 15682 dated 21-06-2023 Rs.30,000/- dated 25-08-2022
	The proposed proprietary name / brand name	**Nexapt 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Nexium 40mg IV powder for solution of M/s GETZ Pharma
	Name and address of API manufacturer.	Sterile India Pvt Ltd. Plot No. 100, Sec-56 Phase-4, Kundli Sonipat (Haryana) India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Esovar 40mg Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
247.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.

	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 16715 dated 05-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Esolip 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Nexium 40mg IV powder for solution of M/s GETZ Pharma
	Name and address of API manufacturer.	Sterile India Pvt Ltd. Plot No. 100, Sec-56 Phase-4, Kundli Sonipat (Haryana) India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Esovar 40mg Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
248.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore

	GMP status of the manufacturer	**M/s English Pharmaceuticals:** Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Evidence of approval of manufacturing facility	**M/s English Pharmaceuticals:** The firm has provided Dry powder injection vials (General) approval.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17754 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sar-Esom 40mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Nexium 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Sterile India Pvt. Ltd Plot No.100, 118-G, Sector-56, Phase-IV, HSIIDC, Kundli District Sonepat, Haryana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore. Manufacturer firm — M/s English Pharmaceuticals. Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name — Epsol 40mg Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
249.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta

		Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 14525 dated 09-06-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Feribac 4.5gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
250.	Name, address of Applicant / Marketing Authorization Holder	**M/s ICU Pharmaceuticals.** **Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Capsule section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13635 dated 01-06-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Xec-Xim 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each caspsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Caricef capsule of M/s Sami
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: CARECEF 400mg capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
251.	Name, address of Applicant / Marketing Authorization Holder	M/s Onyx Pharmaceuticals30-A, Industrial Estate Mansehra
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024 declares availability of Capsule general setion.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13521 dated 31-05-2023 Rs.75,000/- dated 04-05-2023
	The proposed proprietary name / brand name	**Ozonex 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Omeprazole (as enteric coated pellets)...20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Risek capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 019364
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore have already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Sapient Pharma, 123/S, 104/S, Industrial area Kot Lakhpat, Lahore. Manufacturer firm: M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore Brand Name: Gosoft 20mg capsule	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
252.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13515 dated 31-05-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Fropen 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
253.	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories Pvt Ltd.** **10 km, Faisalabad Road, Bikhi, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	GMP status of the manufacturer	GMP certificate issued on 06-10-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on 06-10-2020 declared availability of Lyophilized Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13377 dated 30-05-2023 Rs.30,000/- dated 28-04-2023 & Rs.45,000/- dated 19-05-2023
	The proposed proprietary name / brand name	**Vancova 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….1gm (as lyophilized powder for injection)
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.

	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 1gm Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan Manufacturer firm: M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Brand Name: Vanco 1gm Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
254.	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories Pvt Ltd.** **10 km, Faisalabad Road, Bikhi, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	GMP status of the manufacturer	GMP certificate issued on 06-10-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on 06-10-2020 declared availability of Lyophilized Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13378 dated 30-05-2023 Rs.30,000/- dated 28-04-2023 & Rs.45,000/- dated 19-05-2023
	The proposed proprietary name / brand name	**Vancova 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….500mg (as lyophilized powder for injection)

	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 500mg Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
Manufacturer firm	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
Brand Name	Vanco 500mg Injection

	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
255.	**Deleted due to repition**	
256.	**Deleted due to repition**	
257.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals

		Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13515 dated 31-05-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Fropen 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
258.	Name, address of Applicant / Marketing Authorization Holder	M/s Onyx Pharmaceuticals30-A, Industrial Estate Mansehra
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore

	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 18-01-2024
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020 declares availability of Capsule general setion.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13521 dated 31-05-2023 Rs.75,000/- dated 04-05-2023
	The proposed proprietary name / brand name	**Ozonex 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Omeprazole (as enteric coated pellets)...20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Risek capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 019364
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore have already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Sapient Pharma, 123/S, 104/S, Industrial area Kot Lakhpat, Lahore. Manufacturer firm: M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore Brand Name: Gosoft 20mg capsule	
	Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
259.	Name, address of Applicant / Marketing Authorization Holder	**M/s ICU Pharmaceuticals.** **Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No.

		000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Capsule section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13635 dated 01-06-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Xec-Xim 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each caspsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Caricef capsule of M/s Sami
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name — CARECEF 400mg capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**	
	Decision: Approved as per manufacturer's specifications notified vide Notification no. F.14-1/2022-PEC dated 14-03-2022. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
260.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta

		Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 14525 dated 09-06-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Feribac 4.5gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
261.	Name, address of Applicant / Marketing Authorization Holder	**M/s Aptcure Pvt Ltd** **8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 15682 dated 21-06-2023 Rs.30,000/- dated 25-08-2022
	The proposed proprietary name / brand name	**Nexapt 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium ------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Nexium 40mg IV powder for solution of M/s GETZ Pharma
	Name and address of API manufacturer.	Sterile India Pvt Ltd. Plot No. 100, Sec-56 Phase-4, Kundli Sonipat (Haryana) India.

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Esovar 40mg Injection	
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
262.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited.** **B-23, S.I.T.E. Karachi**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11- 10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 12-06-2017 specifying Dry vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 10032 dated 14-04-2023 Rs.75,000/- dated 30-03-2023
	The proposed proprietary name / brand name	**Cefroline 600mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftaroline Fosamil as L-Arginine…600mg
	Pharmaceutical form of applied drug	Third-generation cephalosporins
	Pharmacotherapeutic Group of (API)	White to off white powder filled in glass vial.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 600mg Injecion, Allergan pharma Ireland, FDA Approved Drug.
	For generic drugs (me-too status)	Zinforo Injection 600mg, Pfizer Pvt Limited. (Reg.# 110515)

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Qingdao Xinnuo Pharmaceutical Chemical
Co., Ltd. 50 meters North Yuanhou Neighborhood
Committee Xifuzhen Street Chenyang Area
Qingdao Shandong, CHINA</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 330th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

<table>
<tr><td>Applicant firm</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Brand Name</td><td>Ceffosa Injection 600mg IV/IM</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>263.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s AGP Limited.
B-23, S.I.T.E. Karachi</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate dated
11-11-2022, based on inspection conducted on 11-
10-2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of grant of section
dated 12-06-2017 specifying Dry vial Cephalosporin section.</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 13526 dated 31-05-2023 Rs.75,000/- dated 30-03-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Ceftabact 2.5gm Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Ceftazidime pentahydrate eq. to Ceftazidime……2gm
Avibactam as Sodium……0.5gm</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Third-generation cephalosporins</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>A White or Light Yellow Sterile free flowing powder Filled in Vials Packed in Unit Carton</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Innovator’s Specification</td></tr>
</table>

<table>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Avycaz 2/0.5g injection Allergan Pharma Limited US FDA Approved drugs</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Zavicefta 2g/0.5g injection Pfizer PVT Limited</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Qilu Antibiotics Pharmaceutical CO., Ltd. No.849
Dongjia town Licheng District China 250105 Jinan,Shangdong Province.</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 330th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Brand Name</td><td>Cefavidime 2.0/0.5G Injection IM/IV</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
<tr><td>264.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Genix Pharma Pvt Ltd.
44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Daneen Pharma Pvt Ltd.
27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate dated 03-04-2019 based on inspection conducted on 08-03-2019.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of GMP certificate dated 03-04-2019 based on inspection conducted on 08-03-
2019 specifying Dry Powder Injectable (Cephalosporin) section</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 13938 dated 05-06-2023 Rs.75,000/- dated 25-05-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Gzid 2.5gm Powder for Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Ceftazidime……2gm
Avibactam Sodium……0.5gm</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Third-generation cephalosporins</td></tr>
</table>

	Pharmaceutical form of applied drug	A White or Light Yellow Sterile free flowing powder Filled in Vials Packed in Unit Carton
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Avycaz 2/0.5g injection Allergan Pharma Limited US FDA Approved drugs
	For generic drugs (me-too status)	Zavicefta 2g/0.5g injection Pfizer PVT Limited
	Name and address of API manufacturer.	M/s Chifeng Addisun Pharmaceutical Co., Ltd. No.3 Minsheng Street, Economic Development Zone of Hongshan District, Chifeng, Inner Mongolia, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Daneen Pharma Pvt Ltd.27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan have already been approved by Registration Board in its 330th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Daneen Pharma Pvt Ltd.27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan Manufacturer firm: M/s Daneen Pharma Pvt Ltd.27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan Brand Name: Avizid Injection 2.5g	
	Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
265.	Name, address of Applicant / Marketing Authorization Holder	**M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	GMP status of the manufacturer	GMP Certificate No.70/2021 DRAP(FID/2061717- 540) Dated 08-09-21
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-10/2012-Lic dated 7th June, 2022 with 3 sections including "Dry Powder Injection (Cephalosporin) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 13381 dated 30-05-2023 Rs.75,000/- dated 07-04-2023
	The proposed proprietary name / brand name	**Titan 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2gm
	Pharmaceutical form of applied drug	Dry powder injection

	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore have already been approved by Registration Board in its 330th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore Brand Name: Welcef 2g IV injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
266.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12605 dated 22-05-2023
	Details of fee submitted	Rs.75,000/- dated 24-01-2023
	The proposed proprietary name / brand name	**Kelac 30mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Ketorolac Tromethamine…30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Section#	Observation	Firm's response
1.3	➢ Latest GMP inspection report of the drug product manufacturer conducted within last three years shall be submitted.	Submitted

1.6.5	➢ Valid DML/GMP certificate of the drug substance manufacturer shall be submitted.	Submitted
3.2.P.1	• Justify the role of ethanol in the applied formulation • Justify the proposed quantity of ketorolac tromethamine 33mg per ampoule against the label claim of 30 mg per ampoule.	• Ethanol is being used as solution stabilizer in very small amount that is in permissible limit. • To ensure the extractable volume of 1 ml, 1.1 ml is filled in each ampoule.
3.2.P.3.3	Justify the performance of terminal sterilization by autoclave while ethanol is used in the formulation	We are conducting terminal sterilization of said productat low temperature 112°C, to meet sterility criteria and ur product stable as per recommended shelf life.
3.2.P.5.1	• Evidence of availability of equipment for the performance of "Particulate Matter In Injections" test shall be submitted	Submitted.
3.2.P.5.3	Performance of specificity parameter shall be submitted in analytical method verification studies.	Submitted
3.2.P.5.4	➢ Submitted batch analysis COA does not include performance of sterility test. ➢ Batch analysis certificates are submitted for different batches form that submitted in section 3.2.P.8.3	Firm has submitted COA along with sterility test performance.
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Compliance Record of HPLC software 21CFR & audit trail reports on product testing ➢ Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

267.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd.** **Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 11792 dated 15-05-2023
	Details of fee submitted	Rs.75,000/- dated 06-12-2022
	The proposed proprietary name / brand name	**Cefit 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefixime as Trihydrate…400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Shawan specs
Evaluation by PEC[II]:		
Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		
268.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd.** **Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 11790 dated 15-05-2023
	Details of fee submitted	Rs.75,000/- dated 06-12-2022
	The proposed proprietary name / brand name	**Cefit 100mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as Trihydrate…100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		
269.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd.** **Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 11791 dated 15-05-2023
	Details of fee submitted	Rs.75,000/- dated 06-12-2022
	The proposed proprietary name / brand name	**Cefit 200mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as Trihydrate…200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		
270.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals.** **Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12211 dated 18-05-2023
	Details of fee submitted	Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.		
271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals.** **Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12212 dated 18-05-2023
	Details of fee submitted	Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

272.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13780 dated 02-06-2023
	Details of fee submitted	Rs.75,000/- dated 05-05-2023
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

273.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18527 dated 24-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-06-2023
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Applied formulation has already been approved in name of M/s Wezen pharma in 331st meeting of Registration Board.

Decision: Registration Board considering the previous approval of applied formulation in name of M/s Wezen Pharmaceuticals Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat, decided to dispose off the instant application.

274.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18528 dated 24-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor

	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

275.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12210 dated 18-05-2023
	Details of fee submitted	Rs.75,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

276.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13779 dated 02-06-2023
	Details of fee submitted	Rs.75,000/- dated 05-05-2023

	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

277.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18523 dated 24-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-06-2023
	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

278.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18524 dated 24-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

Decision: Deferred for submission of reply to above cited shortcomings.

279.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18528 dated 24-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response
3.2.P.8.3	Following shall be submitted: ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Reconcillation record for the imported quantity of Trelagliptin succinate.	

➢ Applied formulation has already been approved in name of M/s Wezen pharma in 331st meeting of Registration Board.

Decision: Registration Board considering the previous approval of applied formulation in name of M/s Wezen Pharmaceuticals Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat, decided to dispose off the instant application.		
280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	GMP status of the firm	Firm has submitted copy of GMP Certificate issued based on inspection conducted on 01-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 14-10-2020 specifying Liquid Injectable (SVP) general section
	Dy. No. and date of submission	Dy.No 17567 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 02-06-2023
	The proposed proprietary name / brand name	**Ferrova 500mg/10ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Iron as Ferric Carboxymaltose…50mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Anti-Anemic
	Reference to Finished product specifications	Innovator
Remarks of Evaluator(II):		
Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		

281.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12899 dated 25-05-2023
	Details of fee submitted	Rs.75,000/- dated 09-02-2023
	The proposed proprietary name / brand name	**Vifor 100mg/5ml Suspension**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Linezolid…100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator's specifications
Evaluation by PEC^{II}:		
Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report of drug product manufacturer, conducted within last three years. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		
282.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12900 dated 25-05-2023
	Details of fee submitted	Rs.75,000/- dated 09-02-2023
	The proposed proprietary name / brand name	**Aziblaze 200mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Azithromycin as Dihydrate…200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC^{II}: M/s Bio Mark has requested for change of Manufacturer of the applied product from M/s Winlet Pharmaceuticals 30-km, Lahore Sargodha Road, Lahore to M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan along with submission of data. Firm has not submitted fee for the submission of new data.		
Decision: Registration Board acceded the request of the firm and approved the instant application for contract manufacturing from M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan. The firm shall submit fee of Rs. 75,000/- for cpre-approval change in drug product manufacturer and submission of new stability daat as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
283.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 14530 dated 09-06-2023
	Details of fee submitted	Rs.225,000/- dated 21-03-2023
	The proposed proprietary name / brand name	**UFI-S 6/0.4 mmg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers
	Reference to Finished product specifications	Innovator

Remarks of Evaluator(Ammar):

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosine HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	
3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	
	• Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	

Decision: Deferred for submission of reply to above cited shortcomings

284.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**

	Name, address of Manufacturing site.	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13769 dated 02-06-2023
	Details of fee submitted	Rs.75,000/- dated 06-06-2022
	The proposed proprietary name / brand name	**Cefilet 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefepime as Hcl with L-Arginine…1gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]: M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore has requested for change of Manufacturer of the applied product from M/s Cure Laboratories Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad to M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad along with submission of data. Firm has also submitted fee for the submission of new data.		
Decision: Registration Board acceded the request of the firm and approved the instant application for contract manufacturing from M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad.		
285.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13770 dated 02-06-2023
	Details of fee submitted	Rs.75,000/- dated 06-06-2022
	The proposed proprietary name / brand name	**Cefilet 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefepime as Hcl with L-Arginine…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]: M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore has requested for change of Manufacturer of the applied product from M/s Cure Laboratories Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad to M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad along with submission of data. Firm has also submitted fee for the submission of new data.		
Decision: Registration Board acceded the request of the firm and approved the instant application for contract manufacturing from M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad.		

Case no. 03 Registration applications for Finished drug product Import (Human)

	Name, address of Applicant / Importer	**M/s AMB HK Enterprises Pvt Ltd.**

286.		**2nd Floor Plaza 60 Commercial, Block-K, Phase I, DHA, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 08-05-2028. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name, address of manufacturer(s)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 29848 dated 21-10-2022
	Details of fee submitted	Rs.150,000/- dated 19-08-2022
	The proposed proprietary name / brand name	**Musculoride injection 1gm/10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Injection Contains: Potassium Chloride for Injection…1gm/10ml
	Pharmacotherapeutic Group of (API)	Electrolyte solution: WHO ATC code B05XA01
	Reference to Finished product specifications	Chinese Pharmacopoeia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of CoPP (No. 20240122) valid till 21-05-2025 issued by Hebei Province Drug Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Hebei Tiangcheng Pharmaceutical Co., Ltd & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA	
Proposed Pack size	10 or 50ampoule/box
Proposed unit price	19.5/ampoule
The status in reference regulatory authorities	LAVOISIER POTASSIUM CHLORIDE 10% (0.10 g/ml) approved by ANSM of France
For generic drugs (me-too status)	Could not be confirmed
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang Street, Economic & Technological Devleopment Zone, Cangzhou, Hebei Province, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.

Pharmaceutical Equivalence	Firm hs submitted comapartive analysis report against Potassium chloride Lavoisier 10% (1gm/10ml) injection of CDM Lavoisier, France.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Borosilicate Glass ampoule
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product since submitted COPP was valid till 09-12-2023.	Firm has submitted scanned copy of CoPP (No. 20240122) valid till 21-05-2025 issued by Hebei Province Drug Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer. Moreover firm has stated that original legalized and valid COpp will b esubmitted as soosn as received form China.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

287.	**Name, address of Applicant / Importer**	**M/s Innovegic Pharmaceuticals.** **Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad**
	Details of Drug Sale License of importer	License No: DSL-1605-ICT/2013 Address: Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad Address of Godown: NA Validity: 16-09-2023. Status: Whole sale distributor
	Name and address of marketing authorization holder (abroad)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name, address of manufacturer(s)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 32811 dated 15-11-2022
	Details of fee submitted	Rs.150,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Microgest-100 Soft Gelatin Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule Contains: Progesterone…….100mg
	Pharmacotherapeutic Group of (API)	Genito urinarysystem and sex hormones ATC: G03DA04
	Reference to Finished product specifications	Innovator specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DA/6-152/2011/16/6188) issued dated 25-08-2020 by DGDA of Bangladesh. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 2 years. **GMP:**Firm has also submitted copy of GMP certificate no. DAl6-15212011/4416 issued by DGDA of Bangladesh , valid till 22-02-2024 for M/s Renata Limited Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA	
Proposed Pack size	3 x 10's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Uprogest capsule of M/s Aspin Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.** Addresses of manufacturing site: Gedian Economic Development District,Ezhou, Hubei 436070, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalence and CDP report against reference product Utrogestan soft gelatin capsule
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Alu-PVC
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

288.	**Name, address of Applicant / Importer**	**M/s Innovegic Pharmaceuticals.** **Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad**
	Details of Drug Sale License of importer	License No: DSL-1605-ICT/2013 Address: Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad Address of Godown: NA Validity: 16-09-2023.

		Status: Whole sale distributor
	Name and address of marketing authorization holder (abroad)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name, address of manufacturer(s)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 31988 dated 07-11-2022
	Details of fee submitted	Rs.150,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Microgest-200 Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule Contains: Progesterone…….200mg
	Pharmacotherapeutic Group of (API)	Genito urinarysystem and sex hormones ATC: G03DA04
	Reference to Finished product specifications	Innovator specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DA/6-152/2011/16/6189) issued dated 25-08-2020 by DGDA of Bangladesh. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 2 years. **GMP:**Firm has also submitted copy of GMP certificate no. DAl6-15212011/4416 issued by DGDA of Bangladesh , valid till 22-02-2024 for M/s Renata Limited Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA	
Proposed Pack size	3 x 10's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Uprogest capsule of M/s Aspin Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.** Addresses of manufacturing site: Gedian Economic Development District,Ezhou, Hubei 436070, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.

Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalence and CDP report against reference product Utrogestan soft gelatin capsule
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Alu-PVC
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC^{II}:

Section no.	Observations	Firm's response
1.3	• Submitted COPP declares the name of product as "Microgest-200 soft gelatin capsule", whereas the Active ingredient per unit dose has been declared as "Progesterone 100mng/capsule". • Submit evidence of dedicated manufacturing facility required for the manufacturing of applied formulation. • Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant firm shall be submitted.	
1.3.4	• Submit valid DSL of the applicant.	
3.2.P.2.1	• Drug excipient compatibility studies shall be provided since the qualitative composition of the formulation is not similar to innovator / reference product. • Justification shall be submitted for the use of preservative agents in the composition of soft gelatin capsule.	
3.2.P.2.2.1	• Justify the comparative dissolution profile sampling time points i.e., 01hr, 02 hr,03hr,06hr,08hr,10hr,12hr,14hr & 16hr , considering the fact that applied product is an immediate release formulation.	
3.2.P.5.1	• Justification shall be submitted for not including "Quantitative rupture test" in the drug product specifications. • Justification shall be submitted for not including "Related substance/Impurity test" in the drug product specifications.	
3.2.P.8.3	Justification shall be submitted for not performing following tests in stability studies: • Quantitative rupture test • Related substance/Impurity test • Microbial contamination test	

Decision: Registration Bord deferred the applications of Microgest-100 Soft Gelatin Capsule & Microgest-200 Soft Gelatin Capsule for submission of reply to above cited shortcomings.

	Name, address of Applicant / Importer	**M/s AMB HK Enterprises Pvt Ltd.**

289.		**2nd Floor Plaza 60 Commercial, Block-K, Phase I, DHA, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0058-066904D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 24-02-2023. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China
	Name, address of manufacturer(s)	M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 33813 dated 23-11-2022
	Details of fee submitted	Rs.150,000/- dated 19-08-2022
	The proposed proprietary name / brand name	**Clinaspor Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5gm Contains: Clindamycin as phosphate ……. 0.1gm
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, macrolides, lincosamides and streptogramins
	Reference to Finished product specifications	In-house specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. Zhejiang20210125) valid till 10-06-2023 issued by Zhejiang Medical Product Drug Administration. The certificate confirms the free sale & GMP status of the product. Firm has also submitted copy of GMP certificate no. ZJ20180101 issued by CFDA , valid till 22-08-2023 for M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA	
Proposed Pack size	5gm x 1's
Proposed unit price	Rs. 215
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Clindacal vaginal cream 2% of M./s Caliph Pharmaceuticals
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

Name, address of drug substance manufacturer	Zhejiang Tiantai Pharmaceutical Co., Ltd. Address: No. No.588, Fengze Road, Tiantai County, Taizhou City, Zhejiang, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against Cleocin cream of M/s Pfizer
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Tube
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product. • Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant firm shall be submitted.	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.
1.3.4	• Submit valid DSL of the applicant.	Submitted
1.5.6	Submit the justification for declaring drug product specifications as "in-House" while the pharmacopoeial monograph is available for the applied formulation.	

Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

290.	**Name, address of Applicant / Importer**	**M/s Al-Habib Pharmaceuticals Plot No. 81, Block B, SMCHS, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 339 Address: **81-B, Block. B, SMCHS, Karachi, Pakistan** Address of Godown: Plotno. 396/7 & 393/8 Sectorr, 7-A KIA Karachi Validity: 18-05-2024 Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China
	Name, address of manufacturer(s)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 35675 dated 08-12-2022
	Details of fee submitted	Rs.150,000/- dated 26-01-2022
	The proposed proprietary name / brand name	**Kunyrin 100mg/Vial Lyophillized Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Leucovorin Calcium…100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. 20210112) valid till 07-11-2023 issued by Haina Medical Product Administration of China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing countries on CoPP is mentioned Pakistan. Firm has also submitted copy of EUDRA GMP certificate no. NL/H 18/2008856A issued by competent Authority of Netherland on basis opf inspection conducted on 16—11-2018 for M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China for the manufacturing operations including Lyophilisates sterile products.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of "Supply Agreement" between M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China & M/s Al-Habib Pharmaceuticals Plot No. 81, Block B, SMCHS, Karachi, Pakistan for the applied product

EVALUATION OF DATA	
Proposed Pack size	1's
Proposed unit price	--
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Cerbios Pharma S.A. Via Figino 6, Barbengo, 6917, Switzerland
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against the reference product of Wesrt-Ward
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	PVC/PE Blister
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	
1.5.1	• Submitted strength in submitted CPP and section1.5.2 is as "Each vial contains Leucovorin calcium 100mg" whereas the innovator drug product approved by US FDA contains Leucovorin calcium eq. 100mg base/vial. Justification shall be submitted for the variation in label claim and strength from the innovator drug product.	

Decision: Deferred for submission of reply to above cited shortcomings.

291.	**Name, address of Applicant / Importer**	**M/s Mehran International.** **498 C, Feroz Shah Mehta Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 1192 Address: **498 C, Feroz Shah Mehta Road, Karachi, Pakistan** Address of Godown: NA Validity: 01-08-2023. Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 31047 dated 01-11-2022
	Details of fee submitted	Rs.150,000/- dated 29-09-2022
	The proposed proprietary name / brand name	**Diclofenac Sodium Suppository 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Suppository Contains: Diclofenac Sodium ……. 50mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	CP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2021071206) valid till 11-07-2023 issued by Yiyuan Market Supervision Administration of China. The certificate confirms the free sale & GMP status of the product and drug product manufacturer respectively Firm has also submitted copy GMP certificate no. SD20180652 issued by Shandong Food and Drug Administration, valid till 29-01-2023 for M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China

	Details of letter of authorization / sole agency agreement	Firm has submitted "Sole Agency Agreement" between M/s Reyoung Pharmaceutical Co. Ltd. No.1, Ruiyang Road, Yiyuan County, Shandong Province, China & M/s Mehran International 498 C, Feroz Shah Mehta Road, Karachi, Pakistan for the applied product
EVALUATION OF DATA		
Proposed Pack size		2 blisters/box
Proposed unit price		--
The status in reference regulatory authorities		Approved by MHRA of UK
For generic drugs (me-too status)		N/A
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer		M/s Ningbo Smart Pharmaeutical Co., Ningbo, China
Module-III Drug Substance:		Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:		Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence		Firm has submitted comparative analysis report against Voltarol suppository
Analytical method validation/verification of product		Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product		Polypropylene bottle
Stability study data of drug product, shelf life and storage conditions		Firm has submitted long term stability data of 3 batches for 36 months and 6 months for three batches.
292.	**Name, address of Applicant / Importer**	**M/s Mehran International.** **498 C, Feroz Shah Mehta Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 1192 Address: **498 C, Feroz Shah Mehta Road, Karachi, Pakistan** Address of Godown: NA Validity: 01-08-2023. Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 31048 dated 01-11-2022
	Details of fee submitted	Rs.150,000/- dated 29-09-2022
	The proposed proprietary name / brand name	**Diclofenac Sodium Suppository 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Suppository Contains: Diclofenac Sodium …… 100mg

	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	CP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2021071206) valid till 11-07-2023 issued by Yiyuan Market Supervision Administration of China. The certificate confirms the free sale & GMP status of the product and drug product manufacturer respectively Firm has also submitted copy GMP certificate no. SD20180652 issued by Shandong Food and Drug Administration, valid till 29-01-2023 for M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Details of letter of authorization / sole agency agreement	Firm has submitted "Sole Agency Agreement" between M/s Reyoung Pharmaceutical Co. Ltd. No.1, Ruiyang Road, Yiyuan County, Shandong Province, China & M/s Mehran International 498 C, Feroz Shah Mehta Road, Karachi, Pakistan for the applied product

EVALUATION OF DATA

Proposed Pack size	2 blisters/box
Proposed unit price	--
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Ningbo Smart Pharmaeutical Co., Ningbo, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against Voltarol suppository
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Polypropylene bottle
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months and 6 months for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	New valid COPP is inprocess of legalization and will be submitted as received. Previously submitted COPP was valid at the time of submission.

Decision: Registration Board approved the applications of Diclofenac Sodium Suppository 50mg & Diclofenac Sodium Suppository 100mg with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for each strength for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

293.	**Name, address of Applicant / Importer**	**M/s Mehran International.** **498 C, Feroz Shah Mehta Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 1192 Address: **498 C, Feroz Shah Mehta Road, Karachi, Pakistan** Address of Godown: NA Validity: 01-08-2023. Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34282 dated 28-11-2022
	Details of fee submitted	Rs.150,000/- dated 29-09-2022
	The proposed proprietary name / brand name	**Paracetamol 150mg Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Suppository Contains: Paracetamol…150mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2021071203) valid till 11-07-2023 issued by Yiyuan Market Supervision Administration of China. The certificate confirms the free sale & GMP status of the product and drug product manufacturer respectively Firm has also submitted copy GMP certificate no. SD20180652 issued by Shandong Food and Drug Administration, valid till 29-01-2023 for M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Details of letter of authorization / sole agency agreement	Firm has submitted "Sole Agency Agreement" between M/s Reyoung Pharmaceutical Co. Ltd. No.1, Ruiyang Road, Yiyuan County, Shandong Province, China & M/s Mehran International 498 C, Feroz Shah Mehta Road, Karachi, Pakistan for the applied product

EVALUATION OF DATA	
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

Name, address of drug substance manufacturer	M/s Henei Jiheng (Group) Pharmaceutical Co., Ltd. Address: No. 1, WeiWu Street, Hengshui Industrial Park Hebei Province, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report againstthe Panadol Suppository
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	PVC/PE Blister
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months and 6 months for three batches.

294.	**Name, address of Applicant / Importer**	**M/s Mehran International.** **498 C, Feroz Shah Mehta Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 1192 Address: **498 C, Feroz Shah Mehta Road, Karachi, Pakistan** Address of Godown: NA Validity: 01-08-2023. Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34289 dated 28-11-2022
	Details of fee submitted	Rs.150,000/- dated 29-09-2022
	The proposed proprietary name / brand name	**Paracetamol 250mg Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Suppository Contains: Paracetamol…250mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2021071204) valid till 11-07-2023 issued by Yiyuan Market Supervision Administration of China. The certificate confirms the free sale & GMP status of the product and drug product manufacturer respectively Firm has also submitted copy GMP certificate no. SD20180652 issued by Shandong Food and Drug Administration, valid till 29-01-2023 for M/s Reyoung Pharmaceutical Co. Ltd.

		No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Details of letter of authorization / sole agency agreement	Firm has submitted "Sole Agency Agreement" between M/s Reyoung Pharmaceutical Co. Ltd. No.1, Ruiyang Road, Yiyuan County, Shandong Province, China & M/s Mehran International 498 C, Feroz Shah Mehta Road, Karachi, Pakistan for the applied product
EVALUATION OF DATA		
Proposed Pack size		As per SRO
Proposed unit price		As per SRO
The status in reference regulatory authorities		Approved by MHRA of UK
For generic drugs (me-too status)		N/A
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer		M/s Henei Jiheng (Group) Pharmaceutical Co., Ltd. Address: No. 1, WeiWu Street, Hengshui Industrial Park Hebei Province, China
Module-III Drug Substance:		Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:		Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence		Firm has submitted comparative analysis report againstthe Panadol Suppository
Analytical method validation/verification of product		Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product		PVC/PE Blister
Stability study data of drug product, shelf life and storage conditions		Firm has submitted long term stability data of 3 batches for 24 months and 6 months for three batches.
295.	**Name, address of Applicant / Importer**	**M/s Mehran International.** **498 C, Feroz Shah Mehta Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 1192 Address: **498 C, Feroz Shah Mehta Road, Karachi, Pakistan** Address of Godown: NA Validity: 01-08-2023. Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34282 dated 28-11-2022

	Details of fee submitted	Rs.150,000/- dated 29-09-2022
	The proposed proprietary name / brand name	**Paracetamol 125mg Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Suppository Contains: Paracetamol…125mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2021071202) valid till 11-07-2023 issued by Yiyuan Market Supervision Administration of China. The certificate confirms the free sale & GMP status of the product and drug product manufacturer respectively Firm has also submitted copy GMP certificate no. SD20180652 issued by Shandong Food and Drug Administration, valid till 29-01-2023 for M/s Reyoung Pharmaceutical Co. Ltd. No.1,Ruiyang Road, Yiyuan County, Shandong Province, China declaring the availability of manufacturing facility for Suppositroy.
	Details of letter of authorization / sole agency agreement	Firm has submitted "Sole Agency Agreement" between M/s Reyoung Pharmaceutical Co. Ltd. No.1, Ruiyang Road, Yiyuan County, Shandong Province, China & M/s Mehran International 498 C, Feroz Shah Mehta Road, Karachi, Pakistan for the applied product

EVALUATION OF DATA	
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Henei Jiheng (Group) Pharmaceutical Co., Ltd. Address: No. 1, WeiWu Street, Hengshui Industrial Park Hebei Province, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report againstthe Panadol Suppository
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	PVC/PE Blister
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	New valid COPP is inprocess of legalization and will be submitted as received. Previously submitted COPP was valid at the time of submission.
3.2.P.2.2.1	• Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	We have followed BP monograph for drug product specification wherein the said tests are not included.
3.2.P.5.1	• Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: i. Uniformity of Dosage units ii. Softening time of lipophilic suppositories iii. Drug Release test	

Decision: Registration Board approved the applications of Paracetamol 150mg Suppository, Paracetamol 250mg Suppository & Paracetamol 125mg Suppository with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter.

296.	**Name, address of Applicant / Importer**	**M/s Biocare Pharmaceutica. 807 Shadman-1, Lahore, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-032069D **Address: 807 Shadman-1, District Lahore**. **Address of Godown:** First floor 8-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. **Validity:** 17-04-2027. **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. **Address:-** Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, PR China. 276017.
	Name, address of manufacturer(s)	Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. **Address Manufacturing site :-** Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, PR China. 276017.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 840 dated 10-01-2023
	Details of fee submitted	Rs.75,000/- dated 30-12-2022
	The proposed proprietary name / brand name	**Bionem 300mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Biapenem…300mg

	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	In-House or Innovator Spec. (National specification issued by China National Medical Products Administration with the approval No. YBH04172014) .
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP with certificate No. 20225016, issued by Shandong Provincial Medical Products Administration (People's Republic of China) valid till 05-6-2024. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing countries on CoPP are mentioned including Pakistan. Firm has also submitted Legalized GMP certificateno. SD20180816 issued by Shandong Food And Drug Administration, in name of Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province valid till 25-11-2024
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of legalized distribution agreement signed by both parties Biocare Pharmaceutica & Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. Agreement clearly mention Aboard License Holder/manufacturer Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., appoints M/s Biocare Pharmaceutica to register/market/sell/Distribute its product Bionem (Biapenem) 0.3 gm in Pakistan. Agreement is Valid with 12 months renewal clause.

EVALUATION OF DATA	
Proposed Pack size	--
Proposed unit price	Rs. 5200/vial-
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Merem 1gm injection of M/s Global (Reg.#038139)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. Address No. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi City, Shandong Province, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference brand: - Omegacin (Biapenem) produced by Meiji Seika Pharma Co., Ltd, Japan.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.

Container closure system of the drug product	Biapenem for Injection is packed in injection vials made of low borosilicate glass tubing covered with halogenated butyl rubber stoppers sealed with aluminum-plastics combination caps.
Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 30°C ± 2°C / 65% ± 5%RH (Zone IVA) of 03 batches (320103001, 320103002, 320103003) is Submitted. • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches (320103001, 320103002, 320103003) is submitted.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority for the drug substance manufacturer.	
3.2.S.4.1	Justification shall be submitted for variation in proposed limits of test of "optical rotation test" i.e., -30° - -36° from that recommended by the innovator literature i.e., -31° - -36°	
3.2.P.2.6	Compatibility study of applied drug product with the recommended re constitution diluents shall be submitted.	
3.2.S.7.3	Justification shall be submitted for not performing test of identification & sterility of during drug substance stability studies.	
3.2.P.3.1	Submitted DML of the drug product manufacturer does not include scope for manufacturing facility of "Carbapenem dry powder injection".	
3.2.P.3.3	Description of the sterility process of the applied product shall be submitted.	
3.2.P.5.1	Justification shall be submitted for variation in proposed limits of test of "pH" i.e., 4 - 6 from that recommended by the innovator literature i.e., 4.5-5.8. Justification shall be submitted for the proposed limit of "Weight variation test" i.e., NMT±7%, with reference to the pharmacopoeial provisions.	

Decision: Deferred for submission of reply to above cited shortcomings.

297.	**Name, address of Applicant / Importer**	**M/s We Care.** **Flat B6, 2nd Floor, Block D-12, Sector G-8 Markaz, Islamabad**
	Details of Drug Sale License of importer	License No. DSL-985-ICT/2013 Address: **Flat B6, 2nd Floor, Block D-12, Sector G-8 Markaz, Islamabad** Address of Godown: NA Validity: 02-12-2022. Status: Whole Sale Distributor
	Name and address of marketing authorization holder (abroad)	M/s PT Dexa Medica. Jl. Jenderal Bambang Utoyo No. 138, Palembang, Indonesia

	Name, address of manufacturer(s)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 4212 dated 14-02-2023
	Details of fee submitted	
	The proposed proprietary name / brand name	**Tripenem 1gm Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem bulk (srterile dry mixture of Meropenem trihydrate with Sodium Carbonate)1.358gm equivalent to Meropenem…1gm
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP (No. RG.01.05.32.321.02.21.2487) dated 08-02-2021, issued by National Agency of Drug and Food Control, Indonesia. The certificate confirms the free sale & GMP status of the product. Firm has also submitted original legalized certificate no. ST.03.05.33.0331.02.21.000448 issued by Indonesian Food And Drug Authority in name of M/s PT Dexa Medica, Jl. Jenderal Bambang Utoyo No. 138, Palembang, Indonesia, declaring that the manufacturing facility of "Cephalosporin sterile Powder for injection and its derivatives (including Carbapenem and Carbacephem derivatives)" are subject to periodic inspection. The said certificate is valid till 01-02-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Letter of Authorization" wherein PT DEXA MEDICA, JI. Jend. Bambang Utoyo No. 138, Palembang Indonesia hereby appoint and authorize GLORIOUS DEXA SINGAPORE PTE. LTD.a limited, 80 Robinson Road #17-02, as an exclusive marketer and distributor of Dexa with the rights to commercialize Dexa's products in certain countries including the territory of Pakistan (hereinafter referred to as "Territory'). Furthermore, as the manufacturer and owner of the product, Dexa hereby authorizes GDS to appoint WE CARE, a company duly organized and existing under the Laws of Pakistan, having its principal office at Flat B 6 2" Floor G-8 Markaz, Islamabad, Pakistan (hereinafter referred to as "WE CARE") as the distributor of applied Product in the Territory and to submit the application of drug registration to the Drug Regulatory Authority of Pakistan and deal in all matter pertaining to the registration for the product.
EVALUATION OF DATA		
Proposed Pack size	--	

Proposed unit price	--
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Merem 1gm injection of M/s Global (Reg.#038139)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Shenzhen Haibin Pharmaceutical Co., Ltd. No. 2003, Shenzhen City, Guangdong Province, People's Republic of China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Pharmaceutical equivalence has beebn submitted against the Meronem injection.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Type I Glass vial
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 75±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.1	Submit evidence of submission of fee.	
1.3	Submit evidence of availability of separate manufacturing facility for the "Carbapenem" dry powder injections".	
1.3.4	• Submit valid DSL of the applicant.	
1.5.2	Label shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem.	
3.2.P.5.1	Justification shall be submitted for including test of "Content of Sodium carbonate" instead of test of "Content of Sodium", as recommended by USP monograph, in submitted drug product specifications.	
3.2.P.8.3	Justification shall be submitted for following: • Not performing test of "Content of Sodium", in drug product stability studies. • Significant change in the results of Assay test during accelerated stability studies.	

Decision: Deferred for submission of reply to above cited shortcomings.

298.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation.** **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 041 Address: **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan** Address of Godown: NA Validity: 19-11-2022. Status: Drug License By way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China

	Name, address of manufacturer(s)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 35670 dated 08-12-2022
	Details of fee submitted	Rs.150,000/- dated 23-09-2022
	The proposed proprietary name / brand name	**Sodium Lactate Riger's Injection 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 500ml Contains: Sodium Lactate…1.55gm Sodium Chloride…3gm Potassium Chloride…0.15gm Calcium Chloride…0.1gm
	Pharmacotherapeutic Group of (API)	Electrolyte
	Reference to Finished product specifications	British Pharmacopoeia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP (No. 20210144), valid till 09-08-2023 issued by Hubei Medical Product Administration. The certificate confirms the free sale status of the product. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection after every 5 years. Firm has also submitted copy of GMP certificate no. HB2190553 issued by issued by Hubei Province Medical Product Administration , valid till 26-11-2024 for M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Agent and Distributor Agreement" between M/s Sohail Corporation & M/s Tianjin King for the applied product valid till 17-06-2026

EVALUATION OF DATA	
Proposed Pack size	500ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved. Lactated Ringer's in Plastic Container by Baxter healthcare
For generic drugs (me-too status)	Ringe Lac Lactated Ringer solution by Otsuka Pakistan
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Sodium Lactate: M/s Anhui Hongye Pharmaceutical Co., Ltd., China Sodium Chloride, Potassium Chloride, Calcium Chloride dihydrate: M/s Tianjin Haiguang Pharmaceutical Co. Ltd., China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.

Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalene report againstseveral brands of Sodium Lactate Ringer's injection solution including of the M/s Shandong Hualu Pharmaceutical Co., Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Polypropylene infusion bottle
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 35±5%RH and 6 months at 40°C±25%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product since submitted COPP was valid till 09-08-2023.	
1.3.4	• Submit valid DSL of the applicant.	
1.5.2	• The quantity of active ingredient shall be stated in terms of the equivalent amount of Calcium chloride dihydrate.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	

Decision: Deferred for submission of reply to above cited shortcomings.

299.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises Pvt Ltd. 2nd Floor Plaza 60 Commercial, Block-K, Phase I, DHA, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 08-05-2028. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name, address of manufacturer(s)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34283 dated 28-11-2022
	Details of fee submitted	Rs.150,000/- dated 23-08-2022
	The proposed proprietary name / brand name	**Paracetamol Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each 100ml Contains: Paracetamol ……. 1gm"
	Pharmacotherapeutic Group of (API)	Antipyretic/NSAID
	Reference to Finished product specifications	CP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. Hebei20210539) dated 20-12-2021, valid till 19-12-2023 issued by Hebei Province Drug Administration. The certificate confirms the free sale & GMP status of the product.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Hebei Tiangcheng Pharmaceutical Co., Ltd & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA

Proposed Pack size	1 glass bottle /box
Proposed unit price	150/1box
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	Provas infusion of M/s Sami Pharmaceuticals
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against Parcetamol 10mg/ml infusion of M/s Atlan Pharma ltd.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Glass bottle
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 9 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC^{II}:

Section#	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	• Original Valid and legalized CoPP is under process. However, it is relevant to mention that at the time of submission CoPP was valid.
1.3.4	• Submit valid DSL of the applicant.	Submitted
3.2.S.2.1	Name of drug substance manufacturer mentioned in this section i.e., Anqiu Lu'an Pharmaceutical Co., Ltd. No. 35, Weixu North Road, Anqiu City Shandong Province, China is different form that mentioned in section 1.6.5 i.e., M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological	Anqiu Lu'an Pharmaceutical Co., Ltd. No. 35, Weixu North Road, Anqiu City Shandong Province, China is the drug substance manufacturer while M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. is the drug product manufcaturer.

	Development Zone, Cangzhou, Hebei, China.	
3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer i.e., M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.	Submitted
3.2.P.7	• Extractable and leachable studies shall be submitted for the container closure system used for applied formulation.	Firm has submitted analysis report for the infusion bottles.
3.2.P.8.3	Long term stability studies shall be submitted till claimed shelf life at Zone IV conditions.	Long term stability studies data till 36th month time point has been submitted.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

300.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises Pvt Ltd. 2nd Floor Plaza 60 Commercial, Block-K, Phase I, DHA, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 08-05-2028. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name, address of manufacturer(s)	M/s Hebei Tiangcheng Pharmaceutical Co., Ltd. No. 18, Jinguang street, Economic & Technological Development Zone, Cangzhou, Hebei, China.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 34283 dated 28-11-2022
	Details of fee submitted	Rs.150,000/- dated 23-08-2022
	The proposed proprietary name / brand name	**Metronidazole 500mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Infusion Contains: Metronidazole ……. 0.5gm
	Pharmacotherapeutic Group of (API)	Imidazole antiobacterial
	Reference to Finished product specifications	BP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP no. 20210506 valid till 23-11-2023 issued by Hebei Province Drug Administration. The certificate confirms the free sale & GMP status of the product.

	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Hebei Tiangcheng Pharmaceutical Co., Ltd & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA

Proposed Pack size	1 bottle
Proposed unit price	Rs. 150/1box
The status in reference regulatory authorities	Approved by TGA of Australia
For generic drugs (me-too status)	Midazol infusion of M/s S.J& G Fazul Ellahie
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Hubei Hongyuan Pharmaceutical Technology Co., Ltd No. 428 Yishui North Road, Fengshan town, Luoptian County, Hubei Province, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against metronidazole Infusion of M.s Baxter healthcare Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Polypropylene bottle
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	• Original Valid and legalized CoPP is under process. However, it is relevant to mention that at the time of submission CoPP was valid.
3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug substance manufacture.	Submitted
3.2.P.7	• Extractable and leachable studies shall be submitted for the container closure system used for applied formulation.	Firm has submitted analysis report for the infusion bottles.
3.2.P.8.3	Justification shall be submitted for not applying stability conditions as recommended by ICH guidelines for "Drug products packaged in semi-permeable" containers.	Firm has submitted stability studies data as per following conditions: Real time: 30^0C + 2^0C /35% RH + 5% Accelerated: 40ºC + 20ºC /NMT 25% RH

Decision: Approved. Firm shall submit original legalied CoPP before issuance of registration letter.

Deferred cases of Finsihed drug Import:

301.	Name, address of Applicant / Importer	M/s Biocare Pharmaceutica 807 Shdman-I, Lahore.

	Details of Drug Sale License of importer	DSL No.: 05-352-0063-032069D Address: Biocare pharamceutica 80 shadman-I district Lahore. Validity: 17/04/2022 Status: License to sell drugs as Distributor
	Name and address of marketing authorization holder (abroad)	M/s Northeast Pharmaceutical Goup Shenyang No. 1 Pharmaceutical Co., Ltd., N0.8, Kunminghu street, Economic & Technological development zone, Shenyang, Liaoning
	Name, address of manufacturer(s)	M/s Northeast Pharmaceutical Group, Shenyang No. 1 Pharmaceutical Co., Ltd., No. 8, Kun Ming Hu street, Economic & Technological Development zone, Shenyang, Liaoning province, China.
	Exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certificate No. 20190073) issued by Liaoning Medical Products Administration valid till 29/07/2020. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP. • Legalized GMP certificate (No. LN20180007) valid till 25/03/2023.	
	Details of letter of authorization / sole agency agreement • Copy of sole agency agreement is submitted whereby M/s Biocare pharmaceutica is appointed as a distributor for the applied product.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 26048 Dated 005/10/2020
	Details of fee submitted	Rs. 50,000/- Dated 20/08/2020
	The proposed proprietary name / brand name	Fosofix Injection 2gm Alternate brand name: Fonyl Fosfix
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Fosfomycin as disodium……..2gm (equivalent to Fosfomycin disodium……2.64g)
	Pharmaceutical form of applied drug	Powder for solution for intravenous injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	In-house
	Proposed Pack size	1’s
	Proposed unit price	Rs. 1000/-
	The status in reference regulatory authorities	Fosfomycin 20mg/ml powder for solution for infusion (2gm) by M/s Infectopharm, MHRA approved.

	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Northeast Pharmaceutical Group Co., Ltd., 29 Shenxi Liudong road, Shenyang Economic and Technical Development zone, China. (GMP certificate No. LN20190041 valid till 15/07/2024)
	Module-III Drug Substance:	Submitted.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 36 months real time stability data at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
	Module-III Drug Product:	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference product, Fosmicn-S manufactured by M/s Meiji Seka Kaisha ltd, Japan.
	Analytical method validation/verification of product	Analyticl method validation studies are submitted.
	Container closure system of the drug product	Injection vials made up of molded soda lime glass, rubber stopper and aluminium -plastic laminated cap
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

- The product in reference country in approved with a primary packaging of 100ml glass bottle while the volume of vial of the applied product is 30ml.
- The firm has submitted Original, legalized and vlaid CoPP (certificate No. 20210024) issued by Liaoning Medical Products Administration valid till 07/01/2023. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP.
- Analytical method verification studies for API performed by drug product manufacturer are not submitted. The firm has stated that the API testing was conducted as per Chinese Pharmacopoeia therefore verification studies are not required. Moreover, the official monograph for API is present in British Pharmacopoeia.

Decision of 308th meeting:

Deferred for of following points;

- Clarification since the product in reference country in approved with a primary packaging of 50ml glass bottle while the volume of vial of the applied product is 30ml.
- Submission of analytical method validation/verification studies of drug substance performed by drug product manufacturer**.**

Evaluation by PEC-I:

- The firm has provided the following reference of the product which is approved with 30ml volume of the vial which is in-lined with the volume of the vial of the applied product.
  Ivozfo (Fosfomycin for injection) (2g, 4g, 8g) by M/s Verity Pharmaceuticals, Ontario, Health Canada Approved.
  IVOZFO™ (fosfomycin for injection) is supplied in clear type-I glass vials with a rubber stopper (bromobutyl rubber) and pull-off cap containing 2 g (in 30 mL vial), 4 g (in 30 mL vial) or 8 g (in 50 mL vial) of fosfomycin, respectively, in packs of 10 vials each.
  https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=97819 (accessed on 12/11/2021 at 7pm)
- As per MHRA, Water for Injections and Glucose Infusion 50 mg/ml (5 %) or Glucose Infusion 100 mg/ml (10 %) may be used as solvent for the reconstitution and dilution while according to HealthCanada, 5% dextrose solution must be used. Whereas both the authorities recommend that Sodium chloride containing solvents must not be used.

- Reconstitution: (MHRA, Ireland & Health Canada)
  Shake the vial prior to the reconstitution to loosen up the powder. Reconstitute the 2 g or 4 g vials with 20ml solvent.
- Dilution (MHRA, Ireland & Health Canada)
  Transfer the reconstituted contents of **2 g vials** into an infusion container with further **30 ml** of solvent.
  Transfer the reconstituted contents of **4 g vials** into an infusion container with further **80 ml** of solvent.
- The frim has submitted analytical method validation studies for Fosfomycin including precision, accuracy, linearity and specificity. The validation studies for impurities have also been submitted.
- As per the provided data, the in-use after reconstitution with 5% and 10% dextrose solution for 12 hours.
- The applied product is developed and tested according to In-House specifications while the official monograph of the product is available in J.P. The comparison of In-house and J.P specificaytions are given below.

Test	**Limits defined by J.P**	**In-house limits**
pH	6.5-8.5	6.5-8.5
Fosfomycin sodium diol (impurity A)	Test not performed	≤ 1%
Clarity of solution	Clear and colorless	Clear and colorless Should not be more pronounced than the reference suspension 1. Any color produced should not be more intense than reference solution yellow 1.
Water	≤ 4%	≤ 2%
Bacterial endotoxins	Less than 0.025EU/mg	Less than 0.033EU/mg
Visible particles	clear and free from foreign insoluble matters (foreign insoluble matter)	Absent
Particulate matter	≤ 6000/container (≥10um) ≤ 600/container (≥25um)	≤ 6000/container (≥10um) ≤ 600/container (≥25um)
Weight variation	Should meet the requirement <6.02>	±5%
Assay	90-110% Cylinder plate method Test Organism: Proteus Sp.	90-110% Cup plate method Test Organism: Micrococcus Luteus Nephelometry test (parallel lines method) Test Organism: Escheritia Coli

Decision of 313th meeting: The Board deliberated that the specifications limits as defined by Japanese Pharmacopoeia are more stringent and tighter than the established In-House specification as well as the method used for the testing of the applied product are also different from the method developed In-House. Therefore, the Board decided to defer the case and directed the firm to submitted all the relevant data according to the monograph present in Japanese Pharmacopoeia.

Firm's response: Firm has submitted as under:
"Our manufacturer has adapted JP (JPXVIII) specification according to the Pakistan DRAP requirements for Fosfomycin sodium 2.0gm." Firm has also provided following documents:

Undertaking letter from manufacturer confirming JP Spec. (JPXVIII).
2. JP Product Specification of Fosfomycin Sodium for Injection.
3. 3 latest batches Signed/Stamp Certificate of Analysis (COA) of Fosfomycin Sodium 2.0 gm as per JP Spec.
4. Updated product development, Description of dosage form with Formulation Development (Pharmaceutical Equivalence).
5. Analytical method of Fosfomycin sodium for injection (JP).
6. Detail JPXVIII Specification & testing method
7. Stability data (Accelerated/Long Term) that fall within parameters of JP Spec.

Decision: Approved with JP specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

302.	Name, address of Applicant / Importer	M/s Biocare Pharmaceutica 807 Shdman-I, Lahore.

	Details of Drug Sale License of importer	DSL No.: 05-352-0063-032069D Address: Biocare pharamceutica 80 shadman-I district Lahore. Validity: 17/04/2022 Status: License to sell drugs as Distributor
	Name and address of marketing authorization holder (abroad)	M/s Northeast Pharmaceutical Goup Shenyang No. 1 Pharmaceutical Co., Ltd., N0.8, Kunminghu street, Economic & Technological development zone, Shenyang, Liaoning
	Name, address of manufacturer(s)	M/s Northeast Pharmaceutical Group, Shenyang No. 1 Pharmaceutical Co., Ltd., No. 8, Kun Ming Hu street, Economic & Technological Development zone, Shenyang, Liaoning province, China.
	Exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certificate No. 20190072) issued by Liaoning Medical Products Administration valid till 29/07/2020. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP. • Legalized GMP certificate (No. LN20180007) valid till 25/03/2023.	
	Details of letter of authorization / sole agency agreement • Copy of sole agency agreement is submitted whereby M/s Biocare pharmaceutica is appointed as a distributor for the applied product.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 30397 Dated 13/11/2020
	Details of fee submitted	Rs. 50,000/- Dated 20/08/2020 (1925409) Rs. 50,000/- dated 23/09/2020 (1925466)
	The proposed proprietary name / brand name	Fosofix Injection 4gm Alternate brand name: Fonyl Fosfix
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Fosfomycin as disodium……..4gm (equivalent to Fosfomycin disodium……5.28g)
	Pharmaceutical form of applied drug	Powder for solution for intravenous injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	In-house
	Proposed Pack size	1’s
	Proposed unit price	Rs. 1700/-
	The status in reference regulatory authorities	Fosfomycin 40mg/ml powder for solution for infusion (4gm) by M/s Infectopharm, MHRA approved.

	For generic drugs (me-too status)	Fosfomycin injection 4gm by M/s Efroze KHI, R.No.004722
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Northeast Pharmaceutical Group Co., Ltd., 29 Shenxi Liudong road, Shenyang Economic and Technical Development zone, China. (GMP certificate No. LN20190041 valid till 15/07/2024)
	Module-III Drug Substance:	Submitted
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 36 months real time stability data at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
	Module-III Drug Product:	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference product, Fosmicin-S manufactured by M/s Meiji Seka Kaisha ltd, Japan.
	Analytical method validation/verification of product	COAs: 10119030002, 10119030003, 10119030.
	Container closure system of the drug product	Injection vials made up of molded soda lime glass, rubber stopper and aluminium -plastic laminated cap
	Stability study data of drug product, shelf life and storage conditions	• 18 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

- The product in reference country in approved with a primary packaging of 100ml glass bottle while the volume of vial of the applied product is 30ml.
- The firm has submitted Original, legalized and vlaid CoPP (certificate No. 20210027) issued by Liaoning Medical Products Administration valid till 07/01/2023. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP.
- Analytical method verification studies for API performed by drug product manufacturer are not submitted. The firm has stated that the API testing was conducted as per Chinese Pharmacopoeia therefore verification studies are not required. Moreover, the official monograph for API is present in British Pharmacopoeia.

Decision of 308th meeting:

Deferred for of following points;

- Clarification since the product in reference country in approved with a primary packaging of 50ml glass bottle while the volume of vial of the applied product is 30ml.
- Submission of analytical method validation/verification studies of drug substance performed by drug product manufacturer**.**
- Submission of real time stability study data according to the conditions of zone IV-A of 03 batches till shelf life since the submitted data is of 18 months only.

Evaluation by PEC-I:

- The firm has provided the following reference of the product which is approved with 30ml volume of the vial which is in-lined with the volume of the vial of the applied product.
  Ivozfo (Fosfomycin for injection) (2g, 4g, 8g) by M/s Verity Pharmaceuticals, Ontario, Health Canada Approved.
  IVOZFO™ (fosfomycin for injection) is supplied in clear type-I glass vials with a rubber stopper (bromobutyl rubber) and pull-off cap containing 2 g (in 30 mL vial), 4 g (in 30 mL vial) or 8 g (in 50 mL vial) of fosfomycin, respectively, in packs of 10 vials each.
  https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=97819 (accessed on 12/11/2021 at 7pm)

- As per MHRA, Water for Injections and Glucose Infusion 50 mg/ml (5 %) or Glucose Infusion 100 mg/ml (10 %) may be used as solvent for the reconstitution and dilution while according to HealthCanada, 5% dextrose solution must be used. Whereas both the authorities recommend that Sodium chloride containing solvents must not be used.
- Reconstitution: (MHRA, Ireland & Health Canada)
  Shake the vial prior to the reconstitution to loosen up the powder. Reconstitute the 2 g or 4 g vials with 20ml solvent.
- Dilution (MHRA, Ireland & Health Canada)
  Transfer the reconstituted contents of **2 g vials** into an infusion container with further **30 ml** of solvent.
  Transfer the reconstituted contents of **4 g vials** into an infusion container with further **80 ml** of solvent.
- The firm has submitted analytical method validation studies for Fosfomycin including precision, accuracy, linearity and specificity. The validation studies for impurities have also been submitted.
- The firm has submitted stability data with the following details;
  24 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches
  06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
  Batches: 4190406, 4190407, 4190408
- As per the provided data, the in-use after reconstitution with 5% and 10% dextrose solution for 12 hours.
- The applied product is developed and tested according to In-House specifications while the official monograph of the product is available in J.P. The comparison of In-house and J.P specificaytions are given below.

Test	**Limits defined by J.P**	**In-house limits**
pH	6.5-8.5	6.5-8.5
Fosfomycin sodium diol (impurity A)	Test not performed	≤ 1%
Clarity of solution	Clear and colorless	Clear and colorless Should not be more pronounced than the reference suspension 1. Any color produced should not be more intense than reference solution yellow 1.
Water	≤ 4%	≤ 2%
Bacterial endotoxins	Less than 0.025EU/mg	Less than 0.033EU/mg
Visible particles	clear and free from foreign insoluble matters (foreign insoluble matter)	Absent
Particulate matter	≤ 6000/container (≥10um) ≤ 600/container (≥25um)	≤ 6000/container (≥10um) ≤ 600/container (≥25um)
Weight variation	Should meet the requirement <6.02>	±5%
Assay	90-110% **Cylinder plate method** Test Organism: Proteus Sp.	90-110% **Cup plate method** Test Organism: Micrococcus Luteus **Nephelometry test (parallel lines method)** Test Organism: Escheritia Coli

Decision of 313th meeting: The Board deliberated that the specifications limits as defined by Japanese Pharmacopoeia are more stringent and tighter than the established In-House specification as well as the method used for the testing of the applied product are also different from the method developed In-House. Therefore, the Board decided to defer the case and directed the firm to submitted all the relevant data according to the monograph present in Japanese Pharmacopoeia.

Firm's response: Firm has submitted as under:
"Our manufacturer has adapted JP (JPXVIII) specification according to the Pakistan DRAP requirements for Fosfomycin sodium 2.0gm." Firm has also provided following documents:

Undertaking letter from manufacturer confirming JP Spec. (JPXVIII).
2. JP Product Specification of Fosfomycin Sodium for Injection.
3. 3 latest batches Signed/Stamp Certificate of Analysis (COA) of Fosfomycin Sodium 2.0 gm as per JP Spec.
4. Updated product development, Description of dosage form with Formulation Development (Pharmaceutical Equivalence).

5. Analytical method of Fosfomycin sodium for injection (JP). 6. Detail JPXVIII Specification & testing method 7. Stability data (Accelerated/Long Term) that fall within parameters of JP Spec.		
Decision: Approved with JP specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.		
303.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories. B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 002 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 15-08-2022 **Status:** by way of wholesaler **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	TÜM EKİP İLAÇ A.Ş; Address: İstanbul Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.55 34956 Tuzla-İSTANBUL/TURKEY
	Name, address of manufacturer(s)	TÜM EKİP İLAÇ A.Ş; Address: Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.63 34956 Tuzla-Istanbul/Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Firm has submitted original, legalized copy of CoPP certificate (No. 2020/2988) dated 13-10-2020 issued by Republic of Turkey Ministry of health and medical education. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 13-10-2022. • Firm has submitted GMP certificate no. 06244 issued by Turkish Medicine & Medical Devices Agency.	
	Details of letter of authorization / sole agency agreement • Firm has submitted copy of letter of authorization from TÜM EKİP İLAÇ A.Ş; Company. The letter shows that the manufacturer appoints M/s Gene-Tech Laboratories to register and market their products in Pakistan.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported product s, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 21170 dated 03-08-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021 & Rs.50,000/- dated 05-07-2021
	The proposed proprietary name / brand name	**Agrabloc 12.5mg/50ml Concentrate Solution for**

		Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml Vial Contains: Tirofiban as hydrochloride monohydrate…12.5mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	B01AC17 Platelet aggregation inhibitors, except heparin
	Reference to Finished product specifications	In house
	Proposed Pack size	12.5mg/50ml, 1 vial per box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aggrastat 250mcg/ml injection approved by MHRA of UK
	For generic drugs (me-too status)	Agraban 12.5mg/50ml of M/s Pharmasol (Reg.106293)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25^{o}C ± 2^{o}C and 60% ± 5% for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of Caelyx injection has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	AGRABLOC 12.5 mg/50 ml IV Concentrate Solution For Infusion is packed with the following primary packaging materials: - 50 ml colorless Type I glass vial - 20 mm bromobutyl red rubber stopper - 20 mm flip-off cover AGRABLOC is supplied as 1 vial with a PIL in box

		containing approved text, batch number and expiration date.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40 ± 2°C, 75 % ± 5 % R.H for 6 months. The real time stability study data is conducted at 30 ± 2°C, 75 % ± 5 % R.H for 24 months.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.3.3	Submit original valid legalized GMP certificate of drug product manufacturer and COPP of applied product issued by relevant regulatory authority of country of origin.	• Firm has submitted copy of GMP certificate no. IT-API/249/H/2022 issue din name of M/s Farmabios S.p.A on basis of inspection conducted on 01-10-2021 by competent authority of Italy, wherein API manufacturing activity of Tirofiban has been endorsed. • Firm has submitted original, legalized CoPP certificate (No. 2023/3145) dated 25-07-2023 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 24-07-2025. • Firm has submitted original legalized GMP certificate no. TR/GMP/2023/150 issued by Turkish Medicine & Medical Devices Agency covering manufacturing operations of Sterile products.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL as per following details: **License No:** 0311 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 30-01-2028 **Status:** by way of wholesaler **Address of Godown:** N/A
3.2.P.2.1	Submit drug-excipient compatibility studies	Agrabloc formulaton differs

	since qualitative composition of applied formulation is different from that of the innovator drug product. Moreover Clarification shall be submitted regarding inclusion of mannitol in master formulation since innovator drug product does not contain it.	from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is differen the pH range of the solution has not changed. Likewise the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that th prdouct retains the same properties as at time of manufacture.
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	Agrabloc and original product's pH is same.
3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization.	Terminal sterilization cannot be applied to solution-type products that are not resistant to autoclave temperature in the final primary packaging the drug solution is sterilized by passing through a suitable bacteria retaining filter after preparation. When the filter integrity test records made before and after this filtration process confirm the performance of the filtration process it is proven that the solution has been fully sterilised at this point. The portion of the manufcaturing process from thi s point until the fully closed finished product will be viewed as an aseptic processin. In other words, aseptic filling and closure will ensure sterility for all vials of the series produced depending on the adequacy of the measures taken at the facility. "In accordance with the general section titled "Methods for the Preparation of Sterile Products", validation studies accordance (including with sterility assurance level study) of the aseptic processes cesses (filling and closing steps) of this product after Sterile filtration are carried out at regular intervals (separately for each dosage form and volume) according to the

		relevant procedure.
3.2.P.8.3	• Long term stability studies on Zone-IV conditions till claimed shelf life shall be submitted for three batches	Firm has submitted long term stability studies data of three batches of applied product at Zone-IVb conditions for 24 months.

Decision of 330th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response:

Section#	Observations	Firm's response
1.3.3	Submit original valid legalized GMP certificate of drug product manufacturer and COPP of applied product issued by relevant regulatory authority of country of origin.	• Firm has submitted copy of GMP certificate no. IT-API/249/H/2022 issue din name of M/s Farmabios S.p.A on basis of inspection conducted on 01-10-2021 by competent authority of Italy, wherein API manufacturing activity of Tirofiban has been endorsed. • Firm has submitted original, legalized CoPP certificate (No. 2023/3145) dated 25-07-2023 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 24-07-2025. • Firm has submitted original legalized GMP certificate no. TR/GMP/2023/150 issued by Turkish Medicine & Medical Devices Agency covering manufacturing operations of Sterile products.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL as per following details: **License No:** 0311 **Address:** 246-B, Block 6,

		P.E.C.H.S, Karachi, Pakistan **Validity:** 30-01-2028 **Status:** by way of wholesaler **Address of Godown:** N/A
3.2.P.2.1	Submit drug-excipient compatibility studies since qualitative composition of applied formulation is different from that of the innovator drug product. Moreover Clarification shall be submitted regarding inclusion of mannitol in master formulation since innovator drug product does not contain it.	Agrabloc formulaton differs from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is differen the pH range of the solution has not changed. Likewise the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that the prdouct retains the same properties as at time of manufacture.
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	Agrabloc and original product's pH is same.
3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization.	Terminal sterilization cannot be applied to solution-type products that are not resistant to autoclave temperature in the final primary packaging the drug solution is sterilized by passing through a suitable bacteria retaining filter after preparation. When the filter integrity test records made before and after this filtration process confirm the performance of the filtration process it is proven that the solution has been fully sterilised at this point. The portion of the manufcaturing process from thi s point until the fully closed finished product will be viewed as an aseptic processin. In other words, aseptic filling and closure will ensure sterility for all vials of the series produced depending on the adequacy of the measures taken at the facility. "In accordance with the general section titled "Methods for the Preparation of Sterile Products", validation studies accordance (including with sterility assurance level study) of the

		aseptic processes cesses (filling and closing steps) of this product after Sterile filtration are carried out at regular intervals (separately for each dosage form and volume) according to the relevant procedure.
3.2.P.8.3	• Long term stability studies on Zone-IV conditions till claimed shelf life shall be submitted for three batches	Firm has submitted long term stability studies data of three batches of applied product at Zone-IVb conditions for 24 months.

Decision of 331st meeting: Deferred for clarification of applied dosage form and formulation with reference to the innovator drug product

Firm's response: Firm has submitted that applied dosage form is "Liquid Concentrate solution for injection" and further stated that Agrabloc formulaton differs from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is different, the pH range of the solution has not changed. Likewise, the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that the prdouct retains the same properties as at time of manufacture.

Decision: Deferred for submission of clarification on scientific grounds for variation in excipients from the innovatr drug product and rationale for use of Mannitol for the intended role in the formulation.

304	**Name and address of Applicant**	**M/s Hakimsons (Impex) (pvt) Ltd. Hakimsons building 19, Wet Wharf road, Karachi.**
	Detail of Drug Sale License	Address:. Hakimsons (Impex) (pvt) Ltd. Hakimsons building 19, Wet Wharf road, Karachi. Validity: 15/09/2017 Status: Drug sale license by the way of wholesale
	Name and address of manufacturer	M/s Bharat serums and vaccines limited, plot No k-27, Jambivili Village, Anand Nagar, Additional MIDC, Ambernnath (East), Thane 421501
	Name and address of marketing authorization holder	M/s Bharat serums and vaccines limited, plot No k-27, Jambivili Village, Anand Nagar, Additional MIDC, Ambernnath (East), Thane 421501
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 2124 Dated 02/12/2014
	Fee including differential fee	Rs. 50,000/- Dated 01/12/2014
	Brand Name +Dosage Form + Strength	AMPHOLIP IV Injection 50mg/10ml (Amphotericcin B lipid complex Injection)
	Composition	Each ml contains: Amphotericin B ……. 5mg Lipids: • Dimyristoylphosphatidylcholine [DMPC]….. 3.4mg • Dimyristophosphatidylglycerol [DMPG as sodium salt]…1.5mg
	Finished Product Specification	In House
	Pharmacological Group	Antifungal
	Shelf life	24 months
	Demanded Price	Rs 16,600/-
	Pack size	1's (10ml vial)
	International availability	Abelcet 5mg/mL Concentrate for Suspension for Infusion by M/s Teva Pharma B.V., MHRA Approved
	Me-too status	Amphogen 50 by Ms Ferozsons, (Reg # 045800) (Imported)

	Detail of certificates attached	Original legalized CoPP (certificate No.COPP/CERT/ KD/ 16842/ 2014/11/6613/29059) certified by food and Drug Administration Maharashtra state, Mumbai, India Valid till 01/04/2016 confirms that the facilities and operations conform to GMP as recommended by WHO at the time of inspection as per CoPP.
	Remarks of the Evaluator.	• Storage conditions: 2-8°C • The firm has claimed In House manufacturing specifications while the product is present in USP/BP.
	Decision of 289th meeting: The Registration Board deferred the case for clarification whether Anti-Fungals are importable from India or otherwise.	
	Decision of 308th meeting: The Board decided to refer the case to DRAP's Authority in light of its decision regarding importability from India.	
	Evaluation by PEC: The Authority in its 128th meeting held on 14-12-2021, while considering the agenda item of "**IMPORT OF ANTI-FUNGAL DRUGS FROM INDIA",** decided as under: "The Authority noted that antimicrobials is a broader category which includes antibiotics, antifungals, antiprotozoals, and antivirals. While, antibiotics are antibacterial substance and are used to treat or prevent bacterial infections, therefore, clarified that anti-fungal products do not fall under definition of antibiotics and are importable from India as per Import Policy Order, 2016 subject to other conditions and requirements as per aforesaid order."	
	Decision of 324th meeting: Deferred for clarification of the dosage form for applied formulation whether liposomal or otherwise .	
	Firm's response: Frim has replied that our product "Amphotericin B is Lipid Complex. Firm has also submitted following reference product approved by MHRA of UK against the applied formulation and dosge form: "Abelcet Lipid Complex 5 mg/mL Concentrate for dispersion for infusion" Amphotericin B Lipid Complex. Each vial contains 5 mg Amphotericin B per mL. **PHARMACEUTICAL FORM:** Concentrate for dispersion for infusion **List of excipients:** L-α-dimyristoylphosphatidylcholine (DMPC) L-α-dimyristoylphosphatidylglycerol (sodium and ammonium salts) (DMPG) Sodium Chloride Water for Injection	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit original legalied CoPP before issuance of registration letter along with fee of The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

305.	**Name, address of Applicant / Importer**	**M/s IBL Health Care Ltd.**
	Details of Drug Sale License of importer	**License No:0312** **Address:** Section-A, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore, **Validity:** 07-04-2024 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Name of exporting country	China

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 20235057) valid till 13-14-2025 issued by Shandong Provincial Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection of once a year. **The name of importing countries on CoPP include Pakistan.**
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized letter of authorisation from M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China. The letter authorises **M/s IBL Health Care Ltd.** ne IBL Centre, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi to submit application to DRAp for registration approval in Pakistan. The authorization letter is issued dated 10-01-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Tracking ID and date of submission	PP6-RH5-T19P dated 29-11-2023
	Details of fee submitted	PKR 150000/- 01-11-2023
	The proposed proprietary name / brand name	**SEVOLIFE 250ml for Inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml bottle contains: Sevoflurane ….. 100%.
	Pharmaceutical form of applied drug	Liquid for inhalation
	Pharmacotherapeutic Group of (API)	General Anaesthesia
	Reference to Finished product specifications	USP
	Proposed Pack size	250ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved.
	For generic drugs (me-too status)	Sevof liquid for inhalation 250ml of M/s Getz (Reg.# 103781)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has comparative studies against Ultane liquid for Inhalation of M/s Abbvie Inc.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type III amber glass bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

Section no.	Observations	Firm's response
3.2.P.8.3	• Justification shall be submitted for Not performing test of all the Organic Impurities, as recommended by USP monograph during drug product stability studies.	

Decision of 333rd meeting: Deferred for submission of reply to the above cited shortcoming.

Firm's response: Firm has submitted stability studies of three batchesfor both accelerated and longterm conditions as per Zone-IVb, wherein tests of related substances have been performed.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Case no. 04 Registration applications considered on priority against Export facilitation:

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

306.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MTI Medical (Pvt.) Ltd. Plot# 586/587, Sundar Industrial Estate**
	Name, address of Manufacturing site.	MTI Medical (Pvt.) Ltd. Plot# 586/587, Sundar Industrial Estate
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 25.05.2023 by DRAP Lahore based on inspection conducted on 31.01.2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-04-2017 specifying Lyophilized vials Injectable (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ sDomestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 22146 dated 08-09-2023
	Details of fee submitted	Rs.30,000/- dated 28-08-2023
	The proposed proprietary name / brand name	**Gluto 600mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Lyophillized Vial Contains: Glutathione Sodium Salt Eq. to Reduced Glutathione ……. 600mg
	Pharmacotherapeutic Group of (API)	Glutathione is an antidot (WHO ATC Code V03AB32)
	Pharmaceutical form of applied drug	Lyophilized powder for Injection
	Reference to Finished product specifications	Innovator/ Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TAD 600mg/4ml of M/s Biomedica Foscama Industria Chimico-Farmaceutica S.p.A Via Morolense, 87 – 03013 Ferentino (Frosinone) Italy.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Hunan Flag Bio-Technology Co., Ltd., No.7 West Lixiang Road, Changsha National Economic & Technical Development Zone, Changsha, Hunan, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product tad 600mg injection by M/s Biomedica, Italy
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Hunan Flag Bio-Technology Co., Ltd., No.7 West Lixiang Road, Changsha National Economic & Technical Development Zone, Changsha, Hunan, China		
API Lot No.	FG02202011048		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9 12,18,24 (Months)		
Batch No.	LG-001	LG-002	LG-003
Batch Size	5000 Vials	5000 Vials	5000 Vials
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 28-01-2021 specifying 20Kg of L-Glutathione reduced. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturer, issued by relevant regulatory authority of country of origin.	Firm ha ssubmitted Business License Enterprises issued by Changsha City Administration for Industry and Commerce.
3.2.S	Submitted import documents are for L-Glutathione reduced whereas this section declares drug substance as Glutathione sodium. Clarification shall be submitted in this regard.	Firm has submitted revised 3.2.S part forL- Glutathione reduced
3.2.P.2.5	Submit compaitibility study of the drug product with reconstitution diluent.	Submitted
3.2.P.5.2	Evidence of availability of Atomic absorption spectrophotemter shal be submitted for performance of test of sodium content.	Submitted

Decision: Registration Board Deferred all the similar formulation/products for seeking opinion from Heads of Oncology Department of NOORI Hospital, Islamabad, KRL Hospital, Islamabad and PIMS.

307.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MTI Medical (Pvt.) Ltd. Plot# 586/587, Sundar Industrial Estate**
	Name, address of Manufacturing site.	MTI Medical (Pvt.) Ltd. Plot# 586/587, Sundar Industrial Estate
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 25.05.2023 by DRAP Lahore based on inspection conducted on 31.01.2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-04-2017 specifying Lyophilized vials Injectable (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 19210 dated 02-08-2023
	Details of fee submitted	Rs.30,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colimate 2 M.I.U Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity…2 MIU
	Pharmacotherapeutic Group of (API)	Colistimethate is a broad-spectrum polymyxin antibiotic
	Pharmaceutical form of applied drug	White to almost white Lyophilized powder filled in transparent glass vials sealed with std. colour alu flip.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Colicraft 2 Million I.U. Lyophilized Injection, Reg # 094751
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Pharmaceutical Co;Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Colistim 1 Million I.U. by Pharmasol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Pharmaceutical Co;Ltd.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	**Primary Packing material** Glass Vial USP Type Rubber stopper **Secondary Packing material** Flip off seal Label Unit carton Leaflet Inner foam		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9 12,18,24 (Months)		
Batch No.	CMT-001	CMT-002	CMT-003
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	12-2019	12-2019	01-2020
Date of Initiation	09-12-2019	24-12-2019	09-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 002) issued by Republic of China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 14-10-2019 specifying 2Kg of Colistimethate sodium. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable as assay is performed by Bio- Assay
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

308.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has letter for General Capsule section. Grant of section approval dated 12-06-2017, specifying General Capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 8795 dated 30-03-2023
	Details of fee submitted	Rs.30,000/- dated 06-03-2023
	The proposed proprietary name / brand name	**Thalix 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Thalidomide …… 100mg
	Pharmacotherapeutic Group of (API)	Other immunosuppressant
	Pharmaceutical form of applied drug	White to off white powder filled in hard gelatin capsule shells.
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Thalido Capsule 100mg of M/s Atco Laboratories, Karachi, Pakistan
	Name and address of API manufacturer.	Changzhou pharmaceutical Factory, 518 Loadong East Road, Changzhou,, Jiangsu Province China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 3 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 3 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Thalido Capsule of M/s Atco with acceptable value of f2.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Changzhou pharmaceutical Factory, 518 Loadong East Road, Changzhou,, Jiangsu Province China.
API Lot No.	ZS 220707
Description of Pack (Container closure system)	Alu – Alu blisters packed in unit cartons with leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	TC04	TC05	TC06
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	22-11-2022	24-11-2022	29-11-2022
No. of Batches	03		

309.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has letter for General Capsule section. Grant of section approval dated 12-06-2017, specifying General Capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 8794 dated 30-03-2023
	Details of fee submitted	Rs.30,000/- dated 06-03-2023
	The proposed proprietary name / brand name	**Thalix 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Thalidomide …….… 50mg
	Pharmacotherapeutic Group of (API)	Other immunosuppressant
	Pharmaceutical form of applied drug	White to off white powder filled in hard gelatin capsule shells.
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Thalido Capsule 50mg of M/s Atco Laboratories, Karachi, Pakistan
	Name and address of API manufacturer.	Changzhou pharmaceutical Factory, 518 Loadong East Road, Changzhou,, Jiangsu Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 3 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 3 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Thalido Capsule of M/s Atco with acceptable value of f2.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Changzhou pharmaceutical Factory, 518 Loadong East Road, Changzhou,, Jiangsu Province China.		
API Lot No.	ZS 220707		
Description of Pack (Container closure system)	Alu – Alu blisters packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC01	TC02	TC03
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	23-11-2022	23-11-2022	23-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has been inspected for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no. Su 20160138 issued by Jiangsu provincial Drug Administration of China, valid till 24-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate no. E-3388082607125 dated 10-11-2022 for 21 Kg of Thalidomide.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for stability studies
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Observation	Firm's response
Submit stability stuides data of 6th month time point	Submitted

Decision: Registration Board approved the applications of Thalix 100mg Capsule & Thalix 50mg Capsule.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

310.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has letter for General Tablets section. Grant of section approval dated 12-06-2017, specifying General Tablet section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 20061 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 27-07-2023
	The proposed proprietary name / brand name	**Toproz 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coted tablet contains: Tofacitinib citrate eq. to Tofacitinib … 10mg
	Pharmacotherapeutic Group of (API)	Antirheumatics
	Pharmaceutical form of applied drug	White, round, biconvex film coated tablet
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xeljanz 10mg Tablet Pfizer Europe, Belgium, U.S. Food and Drug Administration USFDA
	For generic drugs (me-too status)	Tofab 10mg Tablet Genome Pharmaceuticals (Pvt.) Ltd Plot No. 16/1, Industrial Estate Hattar,, Haripur, Pakistan
	Name and address of API manufacturer.	Metrochem API Private Limited Flat No. 302, Bhanu Enclave, Sunder Nagar, Erragadda, Hyderabad – 500038 Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Xeljanz tablet of Pfizer in three dissolution mediums with acceptable f2 value.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Metrochem API Private Limited Flat No. 302, Bhanu Enclave, Sunder Nagar, Erragadda, Hyderabad – 500038 Telangana State, India.		
API Lot No.	TOF.P/22006		
Description of Pack (Container closure system)	Alu – Alu blisters packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	650 Tablets	650 Tablets	650 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

311.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has letter for General Tablets section. Grant of section approval dated 12-06-2017, specifying General Tablet section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 20060 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 27-07-2023

	The proposed proprietary name / brand name	**Toproz 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coted tablet contains: Tofacitinib citrate eq. to Tofacitinib … 5mg
	Pharmacotherapeutic Group of (API)	Antirheumatics
	Pharmaceutical form of applied drug	White, round, biconvex film coated tablet
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xeljanz 5mg Tablet Pfizer Europe , Belgium, U.S. Food and Drug Administration USFDA
	For generic drugs (me-too status)	Tofab 5mg Tablet Genome Pharmaceuticals (Pvt.) Ltd Plot No. 16/1, Industrial Estate Hattar,, Haripur, Pakistan
	Name and address of API manufacturer.	Metrochem API Private Limited Flat No. 302, Bhanu Enclave, Sunder Nagar, Erragadda, Hyderabad – 500038 Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Xeljanz tablet of Pfizer in three dissolution mediums with acceptable f2 value.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Metrochem API Private Limited Flat No. 302, Bhanu Enclave, Sunder Nagar, Erragadda, Hyderabad – 500038 Telangana State, India.		
API Lot No.	TOF.P/22006		
Description of Pack (Container closure system)	Alu – Alu blisters packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	650 Tablets	650 Tablets	650 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has been inspected for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate from DCA Andhra Pradesh valid upto 13-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate no. E-4254486529183 for 50gm of Tofacitinib dated 26-01-2023.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturers, issued by relevant regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate from DCA Andhra Pradesh valid upto 13-11-2023.
3.2.S.4.3	Analytical method verification studies of drug substances shall be submitted from M/s Seraph pharma	Submitted
3.2.S.7.3	Long term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV conditions.	Submitted
3.2.P.8.3	Submit analytical record for the stability studies of the drug product.	Submitted

Decision: Registration Board approved the applications of Toproz 10mg Tablet & Toproz 5mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

312.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan**
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32126 dated 08-11-2022
	Details of fee submitted	Rs.30,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Dapxiga-M 5/1000 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin ….5mg Metformin Hydrochloride….1000mg
	Pharmacotherapeutic Group of (API)	Dapagliflozin …. Anti diabetic (SGLT2 inhibitor) Metformin…. Anti diabetic (biguanides)
	Pharmaceutical form of applied drug	Oblong, biconvex film-coated tablet having "*f*" on one side and plain on other side
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xigduo Tablets 5mg/850mg (EMA Approved)
	For generic drugs (me-too status)	Daplyza-M Tablets 5mg/850mg (M/s Getz Pharma)
	Name and address of API manufacturer.	**Dapagliflozin Propanediol Monohydrate**: M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin Hydrochloride:** M/s Aarti Drugs Limited – India Address: Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. India.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substance Dapagliflozin propanediol monohydrate and Metformin Hydrochloride at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months (Dapagliflozin propanediol monohydrate) and 60 months (Metformin Hydrochloride).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Dissolution Profile of their product against the reference product Dapa-Met Tablets 5mg/850mg manufactured by M/s Hilton Pharma (Pvt.) Ltd Karachi- Pakistan.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin propanediol monohydrate**: M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Hydrocortisone:** M/s Aarti Drugs Limited – India Address: Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. India.396155		
API Lot No.	Dapagliflozin Propanediol Monohydrate: DG20200107-D01-DG06-02 Metformin Hydrochloride: MEF/11010217		
Description of Pack (Container closure system)	02 Alu-Alu Blisters of 07 Tablets packed in cardboard box (Box of 14 tablets)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DMTab-001	DMTab-002	DMTab-003
Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg, for which the inspection was conducted on 25-01-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin Propanediol Monohydrate:** Firm has submitted copy of GMP Issued dated 24-08-2020 valid up to 23-08-2023 issued by National Medical Products Administration. **Metformin Hydrochloride:** Firm has submitted copy of GMP (Certificate No. 23064344) valid up to 20-06-2026 issued by Food and Drug Control

		Administration Gujarat- India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin Propanediol Monohydrate:** Firm has submitted copy of Form 6 # 00607/2020 DRAP(P)/2665 cleared on 30-07-2020 specifying 0.152 kg. The Form 6 is cleared by AD (I&E) DRAP, Peshawar. **Metformin Hydrochloride:** Firm has submitted copy of commercial invoice bearing Diary No.270 cleared on 11-02-2021 specifying 4000.00 kg. The invoice is cleared by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2022-2023 vide Dy. No. 4831 (R&I) dated 07-05-2024 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

313.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Highnoon Laboratories Ltd. Address: 17.5km, Multan Road, Lahore-53700, Pakistan**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued based on the inspection dated 21-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of New section granted on 24/11/2021 for Injectable Ampoule BF (steroid)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	N8E-R3G-ASQY dated January 3rd, 2024,
	Details of fee submitted	Rs.75,000/- dated 16-08-2023
	The proposed proprietary name / brand name	**BETATEC S RESPULES**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of respule contains: Beclometasone dipropionate…….. 0.8mg Salbutamol sulphate 1.928mg equivalent to Salbutamol …….1.6mg
	Pharmaceutical form of applied drug	Suspension for Nebulisation
	Pharmacotherapeutic Group of (API)	Corticosteroid and Selective beta-2-adrenoreceptor agonists
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 ml: 1's, 5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product is registered in Italian Medicine Agency (AIFA), with the brand name "Clenil Compositum" by Chiesi Farmaceutici, Italy.
	For generic drugs (me-too status)	Manufacturer name: Chiesi Farmaceutici, Italy. Importer: Chiesi Pharmaceutical (Pvt.) Ltd. Brand name: Clenil Compositum, Strength: 0.8mg+1.6mg/2ml, Registration number: 021199
	Name and address of API manufacturer.	**Beclomethasone dipropionate:** FARMABIOS S.p.A.Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy. **Salbutamol sulphate:** LUSOCHIMICA SpA – Via Giotto 9 – 23871 Lomagna (LC) – ITALY
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistanhas already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan Manufacturer firm: M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan Brand Name: Becloson S Suspension for Nebulisation 0.8mg + 1.6mg/2ml	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**	
314.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Highnoon Laboratories Ltd.** **Address: 17.5km, Multan Road, Lahore-53700, Pakistan**

	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued based on the inspection dated 21-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of New section granted on 24/11/2021 for Injectable Ampoule BF (steroid)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	BQG-SS8-YR2V dated January 3rd, 2024
	Details of fee submitted	Rs.75,000/- dated 16-08-2023
	The proposed proprietary name / brand name	**Betatec Respules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml respule contains: Beclomethasone dipropionate….. 0.8mg
	Pharmaceutical form of applied drug	Suspension for Nebulisation
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 ml: 1's, 5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product is registered in Italian Medicine Agency (AIFA), with the brand name "Clenil" by Chiesi Farmaceutici, Italy.
	For generic drugs (me-too status)	Manufacturer name: Chiesi Farmaceutici, Italy. Importer: Chiesi Pharmaceutical (Pvt.) Ltd. Brand name: Clenil, Strength: 0.8mg/2ml, Registration number: 014091
	Name and address of API manufacturer.	M/s FARMABIOS S.p.A.Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistanhas already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan Manufacturer firm: M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan Brand Name: Becloson Suspension for Nebulisation 0.8mg/2ml
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 vide Dy. No. 3163 & 3166/R&I dated 20-02-2024 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

315.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s. The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 3GM-W5W-53QY dated March 18th, 2024
	Details of fee submitted	Rs.750,000/- dated 15-02-2024
	The proposed proprietary name / brand name	**UPADA ER 15mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated, extended release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib …… 15mg
	Pharmacotherapeutic Group of (API)	Immunosuppressants, selective immunosuppressants Indications: Rheumatoid arthritis, Psoriatic arthritis, Axial spondyloarthritis, Non-radiographic axial spondyloarthritis (nr-axSpA), Ankylosing spondylitis (AS, radiographic axial spondyloarthritis), Atopic dermatitis, Ulcerative colitis, Crohn's disease
	Reference to Finished product specifications	Innovator Specifications.
EVALUATION OF DATA		
GMP status of the firm		Firm has submitted copy of GMP Certificate based on inspection conducted on 19-07-2022

Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML specifying Tablet general section
Proposed Pack size	As per SRO
Proposed unit price	As per SRO.
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	--
Name and address of API manufacturer.	M/s. Zheiiang Hongyuna Pharmaceutical co., Ltd. Chem&API's Industrial Zone, Linhai, Zhejiang, P.R.China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies have been established against the innovator product Rinvoq prolonged relased tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	UPDT 220901		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	141D05	141D06	141D07
Batch Size	1500 Tablets	1500 Tablets	1500 tablets
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of drug import license issued by AD I&E DRAP,Karachi dated 14-12-2022 specifying 0.14Kg of Upadacitinib
Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

chromatograms, Raw data sheets, COA, summary data sheets etc.	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[II]:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

316.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-05-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy. No 43 dated 02-01-2023
	Details of fee submitted	Rs.30,000/- dated 22-12-2022
	The proposed proprietary name / brand name	**Empaphage-M XR 25mg+1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated tablet contains: Empagliflozin…….. 25mg (as immediate release coating) Metformin HCI, EP ... 1000mg (as extended-release core)
	Pharmacotherapeutic Group of (API)	Used to treat type 2 diabetes
	Pharmaceutical form of applied drug	Film-coated, sustained released Tablets
	Reference to Finished product specifications	Specification as per Innovator's Product
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR Tablets / Manufacturer: Highnoon Laboratories Ltd. Composition: Empagliflozin + Metformin HCl
	Name and address of API manufacturer.	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais, France. **Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Stability study conditions:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Synjardy XR manufactured by Bohringer Ingelheim. Firm has submitted CDP results of their product against the innovator's product Synjardy XR in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais. **Empagliflozin:**

	Fuxin Long Rui Pharmaceutical Co., Ltd.. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	**Metformin HCI:** 1000051073 **Empagliflozin:** H-F-20210605-D01-E-06-02		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PD-01	PD-02	PD-03
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	07-2022	07-2022	07-2022
No. of Batches	03		

317.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-05-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy. No 42 dated 02-01-2023
	Details of fee submitted	Rs.30,000/- dated 22-12-2022
	The proposed proprietary name / brand name	**Empaphage-M XR 12.5mg+1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated tablet contains: Empagliflozin…….. 12.5mg (as immediate release coating) Metformin HCI, EP ... 1000mg (as extended-release core)
	Pharmacotherapeutic Group of (API)	Used to treat type 2 diabetes
	Pharmaceutical form of applied drug	Film-coated, sustained released Tablets
	Reference to Finished product specifications	Specification as per Innovator's Product
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR Tablets / Manufacturer: Highnoon Laboratories Ltd. Composition: Empagliflozin + Metformin HCl
	Name and address of API manufacturer.	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais, France. **Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Stability study conditions:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Synjardy XR manufactured by Bohringer Ingelheim. Firm has submitted CDP results of their product against the innovator's product Synjardy XR in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais. **Empagliflozin:**

	Fuxin Long Rui Pharmaceutical Co., Ltd.. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	**Metformin HCI:** 1000051073 **Empagliflozin:** H-F-20210605-D01-E-06-02		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PD-01	PD-02	PD-03
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	07-2022	07-2022	07-2022
No. of Batches	03		

318.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-05-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 2252 dated 24-01-2023
	Details of fee submitted	Rs.75,000/- dated 13-12-2022
	The proposed proprietary name / brand name	**Empaphage-M XR 10mg+1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated tablet contains: Empagliflozin…….. 10mg (as immediate release coating) Metformin HCI, EP ... 1000mg (as extended-release core)
	Pharmacotherapeutic Group of (API)	Used to treat type 2 diabetes
	Pharmaceutical form of applied drug	Film-coated, sustained released Tablets
	Reference to Finished product specifications	Specification as per Innovator's Product
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR Tablets / Manufacturer: Highnoon Laboratories Ltd. Composition: Empagliflozin + Metformin HCl
	Name and address of API manufacturer.	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais, France. **Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Stability study conditions:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Synjardy XR manufactured by Bohringer Ingelheim. Firm has submitted CDP results of their product against the innovator's product Synjardy XR in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais. **Empagliflozin:**

	Fuxin Long Rui Pharmaceutical Co., Ltd.. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	**Metformin HCI:** 1000051073 **Empagliflozin:** H-F-20210605-D01-E-06-02		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PD-01	PD-02	PD-03
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	07-2022	07-2022	07-2022
No. of Batches	03		

319.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-05-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20063 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 13-06-2023
	The proposed proprietary name / brand name	**Empaphage-M XR 5mg+1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated tablet contains: Empagliflozin…….. 5mg (as immediate release coating) Metformin HCI, EP ... 1000mg (as extended-release core)
	Pharmacotherapeutic Group of (API)	Used to treat type 2 diabetes
	Pharmaceutical form of applied drug	Film-coated, sustained released Tablets
	Reference to Finished product specifications	Specification as per Innovator's Product
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR Tablets 5/1000mg Manufacturer: Highnoon Laboratories Ltd. Composition: Empagliflozin + Metformin HCl Registration No: 105268
	Name and address of API manufacturer.	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais, France. **Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Stability study conditions:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Synjardy XR manufactured by Bohringer Ingelheim. Firm has submitted CDP results of their product against the innovator's product Synjardy XR in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin HCI:** Merck Santé s.a.s. 5, rue Clément Ader F-62100 Calais. **Empagliflozin:**

	Fuxin Long Rui Pharmaceutical Co., Ltd.. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	**Metformin HCI:** 1000051073 **Empagliflozin:** H-F-20210605-D01-E-06-02		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PD-T-01L	PD-T-02P	PD-T-03P
Batch Size	4000 Tablet	4000 Tablet	4000 Tablet
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to PSI report of Glucovance tablet approved in 293rd meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin HCI:** **Merck Santé** Copy of GMP certificate No. 21MPP078HFR01 issued by EUDRA valid till 17/11/2024 **Empagliflozin:** **Fuxin Long Rui Pharmaceutical Co., Ltd..**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCI:** Firm has submitted copy of commercial invoice cleared on 22-02-202. The invoice is cleared by AD (I&E) DRAP. **Empagliflozin:**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing along with chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturer of Empagliflozin, issued by relevant regulatory authority of country of origin.	Firm has submitted cpy of DML issued by NMPA.

3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	Firm has submitted a "Statement letter" from M/s Fuxin Long Rui as under: "We Fuxin Long Rui Pharmaceutical Co., Ltd. (123000, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province, China) guarantee that Empagliflozin has a certain degree of hydrophobicity, and its solubility in water and buffer solution is relatively small. During the dissolution process, particle aggregation is prone to occur, which further prolongs the dissolution time of the sample, reduces solubility, and causes the detection results to fluctuate at the edge of the limit. Therefore, the limit was slightly relaxed at that time. Later, during the testing process, we paid attention to removing agglomeratedparticles from the sample, ensuring that the solubility limit of the sample in water was consistent with the innovator drug product literature. At present, the COA specification for the product has been revised, but DMF has not been updated in a timely manner, resulting in inconsistency between the both. We will submit the updated files immediately."
3.2.S.4.3	Analytical method verification studies of Metformin HCl shall be submitted as per potentiometric method recommended by Eur. Ph monograph.	Submitted.
3.2.P.3.2	Justification shall be submitted along with performance based data for, used of 100% excess of Active coating solution of Empagliflozin.	Empagliflozin is immediate release and being coated on the Mtformin HCl, extended release core. During coating process loss of material occurs that needs to be compensated with the help of excess quantity to finally obtain Empagliflozin label claim.
3.2.P.3.3	Submit details for in-process testing including dissolution test to establish dissolution profile of Metformin HCl at core stage.	Firm has submitted COAs for the analysis of core tablet declaing dissolution results.
3.2.P.5.2	Submitted analytical method validation record of applied product also mentions Sacubitril in acceptance criteria of resolution.	Frim has submitted revised analytical method validation study report.
3.2.P.8.3	Following shall be submitted: • Documents confirming import of Empagliflozin i.e., Commercial	Submitted •

		invoice, attested by AD I&E DRAP shall be submitted. • Analytical record for Assay test performed for stability studies shall be submitted. • Stability studies data for 6th month time point shall be submitted.	

Decision: Registration Board approved the applications of Empaphage-M XR 25mg+1000mg Tablet, Empaphage-M XR 12.5mg+1000mg Tablet, Empaphage-M XR 10mg+1000mg Tablet & Empaphage-M XR 5mg+1000mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 vide diary no. 2419 (R&I) dated 06-02-2024 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

320.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18738 dated 25-07-2023
	Details of fee submitted	Rs.75,000/- dated 19-06-2023
	The proposed proprietary name / brand name	**Mirogab 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirogabalin as Besylate …… 15mg
	Pharmacotherapeutic Group of (API)	Other Analgesics and Antipyretics, Gabapentinoids ATC code: N02BF03 Indications: Diabetic peripheral neuropathic pain & Postherpetic neuralgia.
	Reference to Finished product specifications	Innovator's Specs

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate No.51/2023-DRAP (K) dated 26-07-2023 based on inspection conducted on 22-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying tablet (General) section.
Proposed Pack size	10's, 25's, 50's & 100's
Proposed unit price	As per SRO

The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin) of M/s Daiichi Sankyo, Japan approved by Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
For generic drugs (me-too status)	**N/A**
Name and address of API manufacturer.	Shandong Kehui Pharmaceutical Co., Ltd. Address: No.9a1, Tianheng Road, Gaoqing City, Shandong Province, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per conditions for drug substance to be stored at freezing conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference Tarlige tablet manufactured by Daiichi Sankyo Japan. Firm has submitted CDP results of their product against the reference product Tarlige tablet 2.5mg manufactured by Daiichi Sankyo Japan in 3 dissolution medias.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	B#220916(N-964)		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	653DS01	653DS02	653DS03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	12 - 2022	12 - 2022	12 - 2022
No. of Batches	03		

321.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18078 dated 18-07-2023
	Details of fee submitted	Rs.75,000/- dated 31-05-2023

	The proposed proprietary name / brand name	**Mirogab 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirogabalin as Besylate …… 10mg
	Pharmacotherapeutic Group of (API)	Other Analgesics and Antipyretics, Gabapentinoids ATC code: N02BF03 Indications: Diabetic peripheral neuropathic pain & Postherpetic neuralgia.
	Reference to Finished product specifications	Innovator's Specs

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate No.51/2023-DRAP (K) dated 26-07-2023 based on inspection conducted on 22-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying tablet (General) section.
Proposed Pack size	10's, 25's, 50's & 100's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin) of M/s Daiichi Sankyo, Japan approved by Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
For generic drugs (me-too status)	**N/A**
Name and address of API manufacturer.	Shandong Kehui Pharmaceutical Co., Ltd. Address: No.9a1, Tianheng Road, Gaoqing City, Shandong Province, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per conditions for drug substance to be stored at freezing conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference Tarlige tablet manufactured by Daiichi Sankyo Japan. Firm has submitted CDP results of their product against the reference product Tarlige tablet 2.5mg manufactured by Daiichi Sankyo Japan in 3 dissolution medias.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	B#220916(N-964)
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		652DS01	652DS02	652DS03
Batch Size		2000 tablets	2000 tablets	2000 tablets
Manufacturing Date		12 - 2022	12 - 2022	12 - 2022
No. of Batches		03		
322.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**		
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16839 dated 06-07-2023		
	Details of fee submitted	Rs.75,000/- dated 31-05-2023		
	The proposed proprietary name / brand name	**Mirogab 5mg Tablet**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirogabalin as Besylate …… 5mg		
	Pharmacotherapeutic Group of (API)	Other Analgesics and Antipyretics, Gabapentinoids ATC code: N02BF03 Indications: Diabetic peripheral neuropathic pain & Postherpetic neuralgia.		
	Reference to Finished product specifications	Innovator's Specs		

EVALUATION OF DATA

GMP status of the firm	Firm has submitted copy of GMP certificate No.51/2023-DRAP (K) dated 26-07-2023 based on inspection conducted on 22-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying tablet (General) section.
Proposed Pack size	10's, 25's, 50's & 100's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin) of M/s Daiichi Sankyo, Japan approved by Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
For generic drugs (me-too status)	**N/A**
Name and address of API manufacturer.	Shandong Kehui Pharmaceutical Co., Ltd. Address: No.9a1, Tianheng Road, Gaoqing City, Shandong Province, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per conditions for drug substance to be stored at freezing conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference Tarlige tablet manufactured by Daiichi Sankyo Japan. Firm has submitted CDP results of their product against the reference product Tarlige tablet 2.5mg manufactured by Daiichi Sankyo Japan in 3 dissolution medias.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	B#220916(N-964)		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	651DS01	651DS02	651DS03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	12 - 2022	12 - 2022	12 - 2022
No. of Batches	03		

323.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16840 dated 06-07-2023
	Details of fee submitted	Rs.75,000/- dated 31-05-2023
	The proposed proprietary name / brand name	**Mirogab 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirogabalin as Besylate …… 2.5mg
	Pharmacotherapeutic Group of (API)	Other Analgesics and Antipyretics, Gabapentinoids ATC code: N02BF03 Indications: Diabetic peripheral neuropathic pain & Postherpetic neuralgia.
	Reference to Finished product specifications	Innovator's Specs

EVALUATION OF DATA

GMP status of the firm	Firm has submitted copy of GMP certificate No.51/2023-DRAP (K) dated 26-07-2023 based on inspection conducted on 22-05-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying tablet (General) section.
Proposed Pack size	10's, 25's, 50's & 100's

Proposed unit price	As per SRO
The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin) of M/s Daiichi Sankyo, Japan approved by Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
For generic drugs (me-too status)	**N/A**
Name and address of API manufacturer.	Shandong Kehui Pharmaceutical Co., Ltd. Address: No.9a1, Tianheng Road, Gaoqing City, Shandong Province, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per conditions for drug substance to be stored at freezing conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference Tarlige tablet manufactured by Daiichi Sankyo Japan. Firm has submitted CDP results of their product against the reference product Tarlige tablet 2.5mg manufactured by Daiichi Sankyo Japan in 3 dissolution medias.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	B#220916(N-964)		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	650DS01	650DS02	650DS03
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	12 - 2022	12 - 2022	12 - 2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for SOVIR-C Tablet 400mg (Sofosbuvir), for which the inspection was conducted on 27-10-2020 and the report was presented in 297th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no Lu20220020, valid till 26-06-2027
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import issued by AD I&E DRAP, Karachi dated 21-11-2022 for 350gm of Mirogabalin besylate
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.8.3**	Following shall be submitted: • Long term stability studies data till 6th month time point. • Documents confirming import of drug substance approved by DRAP I&E Office i.e., clearance certificate or attested commercial ionvoice.	Submitted

Decision: Registration Board approved the applications of Mirogab 15mg Tablet, Mirogab 10mg Tablet, Mirogab 5mg Tablet & Mirogab 2.5mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

324.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	Hudson Pharma Private Limited. **Address:** D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75020, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 4-April-2022 based on inspection conducted on 07-October-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-08-2016 specifying plastic ampoules section (BFS Technology).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23964 dated 24-08-2022
	Details of fee submitted	Rs.75,000/- dated 28-07-2022
	The proposed proprietary name / brand name	**Prato Plus Inhalation Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Contains: Ipratropium Bromide…0.5mg Salbutamol Sulphate …… 3mg eq. to Sulbutamol Base …… 2.5mg
	Pharmacotherapeutic Group of (API)	Salbutamol and Ipratropium bromide for obstructive airway disease ATC code: R03A L02
	Pharmaceutical form of applied drug	Nebuliser Solution Clear colourless sterile solution, filled in LDPE ampoule, free from any external particles.
	Reference to Finished product specifications	USP
	Proposed Pack size	Pack Size:5x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Combihale respules by Hudson Pharma Private Limited (Reg.#090971)
	Name and address of API manufacturer.	**Ipratropium:** Olon S.p.A. Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy. **Salbtamol:** Cipla Limited-Patalganga, Plot No.A-33, A-42, A-2 Patalganga Industrial Area, District-Raigad (Maharashtra), INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Pharmaceutical Equivalence is performed against Combivent manufactured by Boehringer Ingelheim.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	9800/03/16 HDP 160180		
Description of Pack (Container closure system)	LDPE Ampoule which is then foil wrapped and packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18J003	18J004	18J005
Batch Size	180 L	180 L	180 L
Manufacturing Date	08-2018	08-2018	08-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Livabel Respules 0.63mg, for which the inspection was conducted on 11th October 2017 and the report was presented in 275th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. IT-API/129/H/2019) dated 01-08-2019 issued by AIFA Italian Medicine Agency. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. Firm has submitted copy of GMP ceritifcate issued bu FDA Maharashtra for Cipla Limited-Patalganga valid

		till 16-02-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 05-04-2017 specifying 1900Kg of Ipratropium Bromide. The invoice is cleared by AD (I&E) DRAP, Karachi dated 07-04-2017 Firm has submitted copy of commercial invoice cleared on 05-10-2016 specifying 1200gm of Ipratropium Bromide. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.3**	Details of product manufactured in the plastic ampoules section (BFS Technology) of M/s Hudson pharma shall be submitted.	Not submitted
2.	**1.5.2**	Label claim in terms of complete salt form of Ipratropium shall be submitted i.e., Ipratropium bromide as monohydrate.	Firm has submitted revised label claim as under: Each ampoule contains: Ipratropium Bromide ……0.5mg (as 0.5218mg Ipratropium Bromide monohydrate) Salbutamol Sulfate……..3.0125mg eq. To Salbutamol base 2.5mg
3.	**1.6.5**	Valid DML/GMP certificate shall be submitted for the M/s Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy.	Sumitted
4.	**3.2.S.4**	• Clarification shall be submitted regarding the claimed specifications for Ipratropium bromide by drug substance manufacturer, whether it is USP, BP, Ph. Eur. or IP.	We (Hudson Pharma Private Limited) are following BP specs. However, Drug substance manufacturer is performing testing as per mentioned Pharmacopoeial specifications i.e. USP, BP and IP depend on vendor requirements. Which is enclosed for your reference.
		• Drug substance details submitted in section 3.2.S for Ipratropium is from M/s Olon S.p.A whereas COAs, have been submitted from M/s Sifavitor. Justification shall be submitted in this regard.	
	Firm has submitted following justification from M/s Olon s.p.a:		

	"Infa Group Spa and its affiliates Labochim Spa and Sifavitor Srl have been acquired in May 2016 by Olon Spa. Beginning January 1st, 2017 Labochim Spa and Sifavitor Srl will be merged by incoporation into Olon Spa All the documents including, but not limited to: Certificate of Analysis, Label, Invoice, Packing List will be retaining the Brand Name, Logo, Plant Address of Labochim and Sifavitor in order to facilitate the change process. The layout of each document is available and will be supplied upon request. The Manufacturing Licenses and the GMP certificates will be available reissued in the new name Olon Spa within first quarter of 2017. All DMFs and CEPs will be promptly updated and submitted to the Regulatory Authorities in order to reflect the name change."		
5.	**3.2.P.1**	Submitted master formulation shall be justified for quantities of Ipratropium bromide and Salbutamol sulphate per batch, with reference to the equivalency factors of salt forms. Submitted master formulation shall declare the contents of Ipratropium bromide in terms of Ipratropium bromide as monohydrate.	Submitted
6.	**3.2.P.2.1**	Submitted formulation development data declares the use of Ipratropium bromide anhydrous form, whereas Innovator drug product has used Ipratropium bromide monohydrate form. Justification shall be submitted in this regard.	There is a typographical error in part P.2 (PD report). Basically it is Ipratropium bromide monohydrate instead of Ipratropium bromide anhydrous form.
7.	**3.2.P.2.2.1**	Justification shall be submitted for not including test of sterility, particulate matter and Uniformity of dosage units in the Pharmaceutical equivalence studies.	Not submitted
8.	**3.2.P.3.2**	Details of sterilisation procedure adopted for the applied formulation shall be submitted.	Sterilization procedure is carried out through 3 step filtration
9.	**3.2.P.5.1**	• Justification shall be submitted for not including test of Leachables and Net fill weight, with reference to USP general chapter <5>.	• Firm has submitted general "Container qualification studies for LDPE" and "Analytical report for the Leachability testing for plastic packaging" • USP general chapter <1664> recommends testing the final drug product for leachables
10.	**3.2.P.6**	• Date of manufacturing of working standards is subsequent to the date of batch release of drug product. • Justification shall be submitted for use of BP grade working standard of Ipratropium Bromide for analysis of drug product as per USP monograph.	• Not submitted • The testing methods for Ipratropium Bromide raw material are outlined in the British Pharmacopoeia (BP), whereas the testing procedures for the finished drug product are specified in the United States Pharmacopeia (USP). To standardize the working standard for drug product testing, a BP grade reference standard is utilized. The

			acceptance of both BP and USP standards ensures compatibility and compliance throughout the manufacturing process.
11.	**3.2.P.8.3**	• Justification for not performing tests of "Leachable", "Net fill weight" & "Water Loss" during drug product stability studies, with reference to USP general chapter <5>. • Justification shall be submitted for not performing stability studies as per conditions recommended for semi-permeable containers by ICH Q1 guidelines. • As per submitted analytical record chromatographic conditions and concentration of standard and sample solution applied for the Assay test during stability studies are not as per the recommendations of USP monograph of "Ipratropium Bromide and Albuterol Sulfate Inhalation Solution". Justification shall be submitted in this regard.	• Firm has referred to general report of "Analytical report for the Leachability testing for plastic packaging" while USP general chapter <1664> recommends testing the final drug product for leachables. • Firm has submitted water loss studies performed during stability studies on basis of initial weight of filled ampoules, whereas submitted drug product specifications does not include any limits for filled weight of ampoules. • Firm has submitted revised drug product analytical procedure without justifying the deviation of stability study performance from USP monograph.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

325.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd.** **44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	Hudson Pharma Private Limited. **Address:** D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75020, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate dated 4-April-2022 based on inspection conducted on 07-October-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-08-2016 specifying plastic ampoules section (BFS Technology).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26567 dated 20-09-2022
	Details of fee submitted	Rs.75,000/- dated 09-09-2022
	The proposed proprietary name / brand name	**Itramide-S Inhalation Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Contains: Ipratropium Bromide…0.5mg Salbutamol Sulphate …… 3mg eq. to Sulbutamol Base …… 2.5mg
	Pharmacotherapeutic Group of (API)	Salbutamol and Ipratropium bromide for obstructive airway disease ATC code: R03A L02
	Pharmaceutical form of applied drug	Nebuliser Solution Clear colourless sterile solution, filled in LDPE ampoule, free from any external particles.
	Reference to Finished product specifications	USP
	Proposed Pack size	Pack Size:5x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Combihale respules by Hudson Pharma Private Limited (Reg.#090971)
	Name and address of API manufacturer.	**Ipratropium:** Olon S.p.A. Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy. **Salbtamol:** Cipla Limited-Patalganga, Plot No.A-33, A-42, A-2 Patalganga Industrial Area, District-Raigad (Maharashtra), INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Pharmaceutical Equivalence is performed against Combivent manufactured by Boehringer Ingelheim.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	9800/03/16 HDP 160180		
Description of Pack (Container closure system)	LDPE Ampoule which is then foil wrapped and packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18J003	18J004	18J005
Batch Size	180 L	180 L	180 L
Manufacturing Date	08-2018	08-2018	08-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Livabel Respules 0.63mg, for which the inspection was conducted on 11th October 2017 and the report was presented in 275th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. IT-API/129/H/2019) dated 01-08-2019 issued by AIFA Italian Medicine Agency. The certificate specifies that the firm is operating at satisfactory level of GMP

		compliance. Firm has submitted copy of GMP ceritifcate issued bu FDA Maharashtra for Cipla Limited-Patalganga valid till 16-02-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 05-04-2017 specifying 1900Kg of Ipratropium Bromide. The invoice is cleared by AD (I&E) DRAP, Karachi dated 07-04-2017 Firm has submitted copy of commercial invoice cleared on 05-10-2016 specifying 1200gm of Ipratropium Bromide. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr.#	Section#	Observation	Firm's response
12.	**1.3.3**	Details of product manufactured in the plastic ampoules section (BFS Technology) of M/s Hudson pharma shall be submitted.	Not submitted
13.	**1.5.2**	Label claim in terms of complete salt form of Ipratropium shall be submitted i.e., Ipratropium bromide as monohydrate.	Firm has submitted revised label claim as under: Each ampoule contains: Ipratropium Bromide ……0.5mg (as 0.5218mg Ipratropium Bromide monohydrate) Salbutamol Sulfate……..3.0125mg eq. To Salbutamol base 2.5mg
14.	**1.6.5**	Valid DML/GMP certificate shall be submitted for the M/s Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy.	Sumitted
15.	**3.2.S.4**	Clarification shall be submitted regarding the claimed specifications for Ipratropium bromide by drug substance manufacturer, whether it is USP, BP, Ph. Eur. or IP.	We (Hudson Pharma Private Limited) are following BP specs. However, Drug substance manufacturer is performing testing as per mentioned Pharmacopoeial specifications i.e. USP, BP and IP depend on vendor requirements. Which is enclosed for your reference.
		Drug substance details submitted in section 3.2.S for Ipratropium is from M/s Olon S.p.A whereas COAs, have been submitted from M/s Sifavitor.	

		Justification shall be submitted in this regard.	
	Firm has submitted following ustification from M/s Olon s.p.a: "Infa Group Spa and its affiliates Labochim Spa and Sifavitor Srl have been acquired in May 2016 by Olon Spa. Beginning January 1st, 2017 Labochim Spa and Sifavitor Srl will be merged by incoporation into Olon Spa All the documents including, but not limited to: Certificate of Analysis, Label, Invoice, Packing List will be retaining the Brand Name, Logo, Plant Address of Labochim and Sifavitor in order to facilitate the change process. The layout of each document is available and will be supplied upon request. The Manufacturing Licenses and the GMP certificates will be available reissued in the new name Olon Spa within first quarter of 2017. All DMFs and CEPs will be promptly updated and submitted to the Regulatory Authorities in order to reflect the name change."		
16.	**3.2.P.1**	Submitted master formulation shall be justified for quantities of Ipratropium bromide and Salbutamol sulphate per batch, with reference to the equivalency factors of salt forms. Submitted master formulation shall declare the contents of Ipratropium bromide in terms of Ipratropium bromide as monohydrate.	Submitted
17.	**3.2.P.2.1**	Submitted formulation development data declares the use of Ipratropium bromide anhydrous form, whereas Innovator drug product has used Ipratropium bromide monohydrate form. Justification shall be submitted in this regard.	There is a typographical error in part P.2 (PD report). Basically it is Ipratropium bromide monohydrate instead of Ipratropium bromide anhydrous form.
18.	**3.2.P.2.2.1**	Justification shall be submitted for not including test of sterility, particulate matter and Uniformity of dosage units in the Pharmaceutical equivalence studies.	Not submitted
19.	**3.2.P.3.2**	Details of sterilisation procedure adopted for the applied formulation shall be submitted.	Sterilization procedure is carried out through 3 step filtration
20.	**3.2.P.5.1**	• Justification shall be submitted for not including test of Leachables and Net fill weight, with reference to USP general chapter <5>.	• Firm has submitted general "Container qualification studies for LDPE" and "Analytical report for the Leachability testing for plastic packaging" • USP general chapter <1664> recommends testing the final drug product for leachables
21.	**3.2.P.6**	• Date of manufacturing of working standards is subsequent to the date of batch release of drug product. • Justification shall be submitted for use of BP grade working standard of Ipratropium Bromide for analysis of drug product as per USP monograph.	• Not submitted • The testing methods for Ipratropium Bromide raw material are outlined in the British Pharmacopoeia (BP), whereas the testing procedures for the finished

				drug product are specified in the United States Pharmacopeia (USP). To standardize the working standard for drug product testing, a BP grade reference standard is utilized. The acceptance of both BP and USP standards ensures compatibility and compliance throughout the manufacturing process.
	22.	**3.2.P.8.3**	• Justification for not performing tests of "Leachable", "Net fill weight" & "Water Loss" during drug product stability studies, with reference to USP general chapter <5>. • Justification shall be submitted for not performing stability studies as per conditions recommended for semi-permeable containers by ICH Q1 guidelines. • As per submitted analytical record chromatographic conditions and concentration of standard and sample solution applied for the Assay test during stability studies are not as per the recommendations of USP monograph of "Ipratropium Bromide and Albuterol Sulfate Inhalation Solution". Justification shall be submitted in this regard.	• Frim has referred to general report of "Analytical report for the Leachability testing for plastic packaging" while USP general chapter <1664> recommends testing the final drug product for leachables. • Firm has submitted water loss studies performed during stability studies on basis of initial weight of filled ampoules, whereas submitted drug product specifications does not include any limits for filled weight of ampoules. • Firm has submitted revised drug product analytical procedure without justifying the deviation of stability study performance from USP monograph.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

326.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi-75700**
	Name, address of Manufacturing site.	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25272 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 17-08-2023
	The proposed proprietary name / brand name	**Vacutec 24/26mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril……..24.3mg

		Valsartan……..25.7mg (as Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Neprilysin Inhibitor (ARNI)
	Reference to Finished product specifications	Innovator Specifications.

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021
Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021 specifying Tablet general section
Proposed Pack size	7's,10's,14's,20's,28's & 30's
Proposed unit price	As per DPC and SRO.
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	Savesto 49/51mg Tablet by Getz Pharma Pakistan (Pvt.) Limited, Reg. No. 093111
Name and address of API manufacturer.	M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Savesto 100 Tablets 24/26mg Getz Pharmaceutical (Pvt.) Ltd. CDP has been performed against the comparator product that is Savesto 24/26mg Tablets Getz Pharmaceutical (Pvt.) Ltd., in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	12200-200303		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD012SECVALT02	22PD013SECVALT03	2PD014SECVALT04
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets

Manufacturing Date	04-2022	04-2022	04-2022

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by AD I&E DRAP,Karachi dated 10-06-2020 specifying 1Kg of Sacubitril+Valsartan
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted , issued by the relevant regulatory authority of country of origin.	
2.	**2.3.R**	➢ Dispensed quantity of drug substance for the manufacturing of trial batches shall be justified against the potency of drug substance determined in batch analysis.	
3.	**3.2.P.5.1**	➢ Justification shall be submitted for the dissolution speifications of NLT Q in 45 minutes whereas Innovator drug product literature approved by USFDA recommends dissolution limits of "NLT Q in 25 minutes"	

Decision: Deferred for submission of reply to above cited shortcomings.

327.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi-75700**
	Name, address of Manufacturing site.	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25273 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 17-08-2023
	The proposed proprietary name / brand name	**Vacutec 49/51 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…48.6mg Valsartan…51.4mg

		(as Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Neprilysin Inhibitor (ARNI)
	Reference to Finished product specifications	Innovator Specifications.

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021
Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021 specifying Tablet general section
Proposed Pack size	7's,10's,14's,20's,28's & 30's
Proposed unit price	As per DPC and SRO.
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	Savesto 49/51mg Tablet by Getz Pharma Pakistan (Pvt.) Limited, Reg. No. 093111
Name and address of API manufacturer.	M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Savesto 100 Tablets 49/51mg Getz Pharmaceutical (Pvt.) Ltd. CDP has been performed against the comparator product that is Savesto 49/51mg Tablets Getz Pharmaceutical (Pvt.) Ltd., in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	12210-211201		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD184SVALS01	22PD185SVALS02	22PD186SVALS03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	11-2022	11-2022	11-2022

No. of Batches	02
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of drug import license no. K-712746664269 issued by AD I&E DRAP,Karachi dated 18-07-2022 specifying 3Kg of Sacubitril+Valsartan.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted , issued by the relevant regulatory authority of country of origin.	
2.	**2.3.R**	➢ Dispensed quantity of drug substance for the manufacturing of trial batches shall be justified against the potency of drug substance determined in batch analysis.	
3.	**3.2.P.5.1**	➢ Justification shall be submitted for the dissolution speifications of NLT Q in 45 minutes whereas Innovator drug product literature approved by USFDA recommends dissolution limits of "NLT Q in 25 minutes"	
4.	**3.2.P.8.3**	➢ Clearance certificate issued by DRAP I&E office for the import of drug substance shall be submitted.	

Decision: Deferred for submission of reply to above cited shortcomings.

Case no. 05 Registration applications of New DML/New Section

- M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan has been granted additional section of "Tablet (general section)" dated 21-12-2023 upon approval from CLB in its 292nd meeting

328.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan,**
	Name, address of Manufacturing site.	M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 2RV-XRH-XJAA dated March 6th, 2024
	Details of fee submitted	Rs.30,000/- dated 2024-02-15
	The proposed proprietary name / brand name	**Levo Biz Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contain: Levofloxacin as hemihydrate ..500mg
	Pharmacotherapeutic Group of (API)	bactericidal antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
329.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan,**
	Name, address of Manufacturing site.	M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: HQD-BHU-X7SJ dated March 19th, 2024
	Details of fee submitted	Rs.30,000/- dated 2024-02-15
	The proposed proprietary name / brand name	**Cipro Biz Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as HCl …… 500mg
	Pharmacotherapeutic Group of (API)	bactericidal antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
330.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan,**
	Name, address of Manufacturing site.	M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 9SU-RLN-25MU dated March 6th, 2024
	Details of fee submitted	Rs.30,000/- dated 2024-02-15
	The proposed proprietary name / brand name	**Cipro Biz Tablet 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as HCl …… 250mg
	Pharmacotherapeutic Group of (API)	bactericidal antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
331.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan,**
	Name, address of Manufacturing site.	M/s World Biz Pharmaceuticals Plot No. 340 Phase-II, Industrial Estate, Multan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: HR1-MB3-3EQ8 dated March 14th, 2024
	Details of fee submitted	Rs.30,000/- dated 2024-02-15
	The proposed proprietary name / brand name	**Moxi Biz Tablet 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCl …… 400mg
	Pharmacotherapeutic Group of (API)	bactericidal antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

- M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore has been granted new section of "Eye Drop (general section)" dated 14-10-2020.

332.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 5H1-Y7A-GDHJ dated May 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 2023-09-13
	The proposed proprietary name / brand name	**Cunsof (Preservative free) Ophthalmic Solution EQ 2% BASE; EQ 0.5% BASE.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Ophthalmic Solution containing: Dorzolamide as Hydrochloride ..... 20 mg. Timolol as Maleate ..... 5 mg.
	Pharmacotherapeutic Group of (API)	Carbonic Anhydrase Inhibitor with a Beta-Adrenergic Receptor Blocking Agent.
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Vizidor Duo 20 mg/ml + 5 mg/ml, eye drops solution, MHRA approved.
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	**Dorzolamide HCl:** M/s Neuland Laboratories Ltd. Unit-I, Sy. No. 347, 473,474,490/2 Veerabhadraswamy TEMPLE ROAD, Bhonthapalli Village, Gummadidala Mandal, Sangareddy Distric, Telangana, India. **Timolol maleate:** M/s FDC Limited, Plot No.19 & 20/2, M.I.D.C Industrial Area, Village Dhatav, Roha-402 116, District Raigad, Maharashtra State, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the Cosopt PF Opthalmic solution.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	**Dorzolamide HCl:** DZ10521015 **Timolol maleate:** 021D026
Description of Pack (Container closure system)	Plastic bottle

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	--
Batch Size	2000 units	2000 units	--
Manufacturing Date	12-2022	12-2022	--
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dorzolamide HCl:** Firm has submitted copy of EUdra GMP certificate no. "sukls1L6019/2022" valid till 27-07-2025. **Timolol:** Firm has submitted copy of GMP certificate no." NEW-WHO-MP/CERTIKD/104350/2021/11/3716" valid till 03-09-2024 issued by FDA Maharashtra India.
Documents for the procurement of API with approval from DRAP (in case of import).	**Dorzolamide HCl:** Firm has submitted loan letter of Dorzolamide from Pacific Pharmaceuticals Ltd., dated with copy of ADC attested commercial invoice dated: 08-12-2021 in name of Pacific Pharmaceuticals Ltd. **Timolol:** Firm has submitted loan letter of Timolol maleate from Pacific Pharmaceuticals Ltd., dated: 12-08-2022 With copy of ADC attested commercial invoice dated: 04-02-2022 in name of Pacific Pharmaceuticals Ltd.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC[II]:

- Differential fee of Rs. 45,000 shall be submitted since applied formulation has not been registered previously in preservative free presentation.

Decision: Approved. Firm shall submit differential fee of Rs. 45,000/- before issuance of registration letter since applid formulation is not previously registered in Pakistan.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- CLB in its 278th meeting held on 10 – 11 December, 2020 has approved grant of new DML, in name of M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, including Capsuel general section.

333.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**

	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 5H1-Y7A-GDHJ dated May 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Fluzole 50mg/ 5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains; Fluconazole.....50mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	BP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Dry powder suspension general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	US FDA Approved
For generic drugs (me-too status)	Diflucan suspension of Pfizer Pakistan Limited
Name and address of API manufacturer.	M/s Virupaksha Organics Ltd. SY, No. 10,Gaddapotharam village,Jinnaram Mandal,sangareddy District Tilanganna state India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Diflucan suspension
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	AFLNC0822095		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT61	24AT62	24AT63

Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	--
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC^{II}:

- Drug product stability studies data for 6th month time point shall be submitted.
- Documents confirming of procurement of drug substance with the approval of DRAP shall be submitted since submitted documents are of Famotidine.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Firm's response:

- Fluconazole API manufactured by VIRUPAKSHA ORGANICS LTD. India has been Borrowed from M/s Seraph Pharmaceuticals. Complete documets with following details are attached 1. Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals 2. Clearance certificate no. 294168686527426 in name of M/s Seraph pharma dated October 7, 2022,
- Valid DL of drug substance manufacturer has been submitted.

Decision: Approved. Registration Board **authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

334.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 9S2-GAU-Z26L dated May 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Fluzole 150mg capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains; Fluconazole …….. 150mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	BP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of capsule general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	MHRA Approved
For generic drugs (me-too status)	Diflucan 150mg capsules, Manufacturer: Pfizer Pakistan Limited
Name and address of API manufacturer.	M/s Virupaksha Organics Ltd. SY, No. 10,Gaddapotharam village,Jinnaram Mandal,sangareddy District Tilanganna state India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Diflucan 150mg capsules
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	AFLNC0822095		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT25	24AT26	24AT27
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	--
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC^{II}:

- Drug product stability studies data for 6th month time point shall be submitted.
- Documents confirming of procurement of drug substance with the approval of DRAP shall be submitted since submitted documents are of Famotidine.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Firm's response:

- Fluconazole API manufactured by VIRUPAKSHA ORGANICS LTD. India has been Borrowed from M/s Seraph Pharmaceuticals. Complete documets with following details are attached 1. Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals 2. Clearance certificate no. 294168686527426 in name of M/s Seraph pharma dated October 7, 2022,
- Valid DL of drug substance manufacturer has been submitted.

Decision: Approved. Registration Board **authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

335.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: QSU-4V5-QZG5 dated May 27th, 2024,
	Details of fee submitted	Rs.30,000/- dated 2024-05-22
	The proposed proprietary name / brand name	**KETOREIN Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; α-Ketoanalogue to isoleucine (Calcium-salt) ..... 67 mg α-Ketoanalogue to leucine (Calcium-salt) …….. 101 mg α-Ketoanalogue to phenylalanine (Calcium-Salt) …… 68 mg

		α-Ketoanalogue to valine (Calcium-Salt) …… 86 mg α-hydroxyanalogue to DL-methionine (Calcium-Salt)..… 59 mg L-lysine acetate...105mg corresponding to L-lysine.…...75 mg L-threonine ……...……. 53 mg L-tryptophan ……..... 23 mg L-histidine ……..... 38 mg L-tyrosine ……. 30 mg Total nitrogen content per tablet ……. 36 mg Calcium content per tablet ……...1.25mmol = 50 mg
	Pharmacotherapeutic Group of (API)	Amino acids, including combinations with polypeptides
	Reference to Finished product specifications	Specifications as per Innovator

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Ketosteril Tablets of M/s Fresenius kabi approve dy Bfarm of Germany.
For generic drugs (me-too status)	Ketoalfa tablets of M/s Genome Pharmaceuticals (Pvt.) Ltd. Address: Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Haripur.
Name and address of API manufacturer.	➢ M/s Cleargreens Pharmaceuticals (Pvt.) Ltd. 001, Dev Prime Near Vodafone Tower, Corporate Road Makarba, Railway Crossing, Prahlad Nagar, Ahmedabad, Gujarat 380051, India α-Ketoanalogue to isoleucine (Calcium-salt) α-Ketoanalogue to leucine (Calcium-salt) α-Ketoanalogue to phenylalanine (Calcium-Salt) α-Ketoanalogue to valine (Calcium-Salt) α-Hydroxyanalogue to DL-methionine (Calcium-Salt) ➢ M/S: Zhangjiagang Huachang Pharmaceutical Co., Ltd. Address: No.1, Nanhai Road, Yangze River International Chemical Industrial Park, Zhangjiagang city, Jiangsu Province, P.R. (China) L-lysine acetate L-threonine L-tryptophan L-histidine L-tyrosine
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.

Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Ketosteril tablet of M/s Fresenius by quantitative determination of Calcium release of both products in dissolution medium of physiological pH 1.2, 4.5 & 6.8.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	SC16-20231002 SC11-20230801 SC43-20230901 SC38-20231101 SC09-20231001		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT64	24AT65	24AT66
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food And Drug Control Administration, Gujarat, India in name of M/s Cleargreens Pharmaceuticals (Pvt.) Ltd. valid upto 08-01-2025. Firm has submitted copy of DML no. 20160493 issued by Jiangsu Province Drug Administration valid upto 14-01-2027 in name of M/s Zhangjiagang Huachang Pharmaceutical Co., Ltd.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate no. E-7554086521268 & E-6637186524621 issued in name of M/s Seraph Pharma dated 12-12-2023 & 18-09-2023 respectively for import of the drug substances used in the applied formulationalong with Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A

Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC[II]:

- Drug product stability studies data for 6th month time point shall be submitted.
- Complete analytical procedure shall be submitted for the performance of dissolution test.
- Evidence of availability of Atomic Absorption spectrophotometer required for the determination of Calcium content in dissolution test shall be submitted.
- Analytical record for the performance of Dissolution test shall be submitted.

Firm's response: Firm has submitted following:

- Analytical procedure for the performance of dissolution test by potentiometric method aong with analytical record for performance of Dissolution test.

Decision: Approved. **Registration Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

336.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: M6T-R4W-7MWL dated May 16th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-AV 5mg/ 80mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) .....5mg Valsartan 80mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs) and Angiotensin II receptor blockers (ARBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Exforge® of Novartis Pharmaceuticals UK Ltd.(MHRA Approved)
For generic drugs (me-too status)	Exforge tablets Manufacturer of Novartis Pharma(Pakistan)Limited

Name and address of API manufacturer.	Amlodipine: Aurore Life sciences (Pvt.) Ltd. Plot # 68, 69, 2nd Floor, Jubilee Heights, Besides Shilparamam, Madhapur, Hyderabad, Telangana, India Valsartan: M/S: Zhejiang Tianyu Pharmaceutical co., Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Exforge tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	1000141191 10252-230710-01		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT13	24AT14	24AT15
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

337.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: ZJ8-N7P-6EDG dated May 16th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-AV 10mg/ 160mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) 10mg

		Valsartan 160mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs) and Angiotensin II receptor blockers (ARBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Exforge® of Novartis Pharmaceuticals UK Ltd.(MHRA Approved)
For generic drugs (me-too status)	Exforge tablets Manufacturer of Novartis Pharma(Pakistan)Limited
Name and address of API manufacturer.	Amlodipine: Aurore Life sciences (Pvt.) Ltd. Plot # 68, 69, 2nd Floor, Jubilee Heights, Besides Shilparamam, Madhapur, Hyderabad, Telangana, India Valsartan: M/S: Zhejiang Tianyu Pharmaceutical co., Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Exforge tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	1000141191 10252-230710-01		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT19	24AT20	24AT21
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	01-2024	01-2024	01-2024

No. of Batches	03	
338.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: PWP-XRQ-MTRD dated May 16th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-AV 5mg/ 160mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) .....5mg Valsartan 160mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs) and Angiotensin II receptor blockers (ARBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Exforge® of Novartis Pharmaceuticals UK Ltd.(MHRA Approved)
For generic drugs (me-too status)	Exforge tablets Manufacturer of Novartis Pharma(Pakistan)Limited
Name and address of API manufacturer.	Amlodipine: Aurore Life sciences (Pvt.) Ltd. Plot # 68, 69, 2nd Floor, Jubilee Heights, Besides Shilparamam, Madhapur, Hyderabad, Telangana, India Valsartan: M/S: Zhejiang Tianyu Pharmaceutical co., Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Exforge tablet

Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STUDY DATA			
API Lot No.	1000141191 10252-230710-01		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT16	24AT17	24AT18
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by DCA Telangana, valid upto 25-03-2026. Firm has submitted copy of DML no. 20050431 issue dby Zhejiang Province Food and Drug Administration valid upto 16-6-2025.		
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate issued in name of M/s Seraph Pharma dated 20-6-2023 for 10Kg of Amlodipine besylate and dated 27-11-2023 for 100 Kg of Valsartan along with Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals.		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Evaluation by PEC^{II}: Firm has initially submitted drug product stability studies data till 3rd month time point only.			
Decision: Registration Board approved the applications of Cardi-AV 5mg/ 80mg Tablets , Cardi-AV 10mg/ 160mg Tablets & Cardi-AV 5mg/ 160mg Tablets. Furthermore, Registration Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			

339.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 3UV-A37-GZ77 dated May 6th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-A 5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) 5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Norvasc 5mg tabletsManufacturer:M/s Pfizer Laboratories Limited (USFDA Approved)
For generic drugs (me-too status)	Norvasc 5mg tablets Manufacturer:M/s Pfizer Laboratories Limited
Name and address of API manufacturer.	Aurore Life sciences (Pvt.) Ltd. Plot # 68, 69, 2nd Floor, Jubilee Heights, Besides Shilparamam, Madhapur, Hyderabad, Telangana, India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Norvasc tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	1000141191
Description of Pack (Container closure system)	Alu-Alu foil
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT01	24AT02	24AT03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

340.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 31V-M1P-ZG9A dated May 27th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-A 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) 10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Norvasc 10mg tabletsManufacturer:M/s Pfizer Laboratories Limited (USFDA Approved)
For generic drugs (me-too status)	Norvasc 10mg tablets Manufacturer:M/s Pfizer Laboratories Limited
Name and address of API manufacturer.	Aurore Life sciences (Pvt.) Ltd. Plot # 68, 69, 2nd Floor, Jubilee Heights, Besides Shilparamam, Madhapur, Hyderabad, Telangana, India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Norvasc tablet

Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STUDY DATA			
API Lot No.	1000141191		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT04	24AT05	24AT06
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by DCA Telangana, valid upto 25-03-2026.		
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate issue din name of M/s Seraph Pharma dated 20-6-2023 for 10Kg of Amlodipine besylate along with Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals.		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Evaluation by PEC[II]: Firm has initially submitted drug product stability studies data till 3rd month time point only.			
Decision: Registration Board approved the applications of Cardi-A 5mg Tablets & Cardi-A 5mg Tablets. Furthermore, Registration Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			
341.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**	
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,	
	Status of the applicant	☒ Manufacturer	

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: BLU-5S5-HS31 dated 16th March, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-V 80mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Valsartan.....80mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by MHRA
For generic drugs (me-too status)	Valtec Tablets 80mg of M/s Tabros Pharma (Pvt.) Ltd.
Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical co., Ltd. No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang, Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Valtec tablet of M/s Tabros
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	10252-230710-01		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT10	24AT11	24AT12
Batch Size	1000 tablets	1000 tablets	1000 tablets

Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

342.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: BTP-PYB-HR4D dated 16th March, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Cardi-V 40mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Valsartan.....40mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by MHRA
For generic drugs (me-too status)	Valtec Tablets 40mg of M/s Tabros Pharma (Pvt.) Ltd.
Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical co., Ltd. No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang, Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Valtec tablet of M/s Tabros
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	10252-230710-01
Description of Pack (Container closure system)	Alu-Alu foil
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT07	24AT08	24AT09
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted DML issued by Zhejiang Province Food and Drug administration valid till 16-06-2025
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate issue din name of M/s Seraph Pharma dated 27-11-2023 for 100Kg of Valsartan along with Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC[II]: Firm has initially submitted drug product stability studies data till 3rd month time point only.

Decision: Registration Board approved the applications of Cardi-V 80mg Tablets & Cardi-V 40mg Tablets Furthermore, Registration Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

343.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 6JG-S5D-37S2 dated May 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Etoroxib 60mg tablets**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Etoricoxib.....60mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory & Anti-rheumatic Products Non-Steroids
	Reference to Finished product specifications	Specification as per Innovator product

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Starcox 90mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited
Name and address of API manufacturer.	M/s. Seutic Labs Pvt. Ltd. Plot No 4-P2, Sy. No 129, Gadwanthi Village, Humnabad Industrial Area, Humnabad, Bidar, Karnataka-585330 (India)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Starcox tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	TRT VI23090		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT73	24AT74	24AT75
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		

344.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**
	Name, address of Manufacturing site.	M/s Solaris Life Sciences Private Limited Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 6X8-XTR-TTLJ dated May 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 29-04-2024
	The proposed proprietary name / brand name	**Etoroxib 90mg tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Etoricoxib.....90mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory & Anti-rheumatic Products Non-Steroids
	Reference to Finished product specifications	Specification as per Innovator product

EVALUATION OF DATA	
GMP status of the firm	New DML granted on 17-01-2024
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Tablet general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Starcox 90mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited
Name and address of API manufacturer.	M/s. Seutic Labs Pvt. Ltd. Plot No 4-P2, Sy. No 129, Gadwanthi Village, Humnabad Industrial Area, Humnabad, Bidar, Karnataka-585330 (India)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the Starcox tablet
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	TRT VI23090		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	24AT76	24AT77	24AT78

Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2024	01-2024	01-2024
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate issued by Drug Control Department , Government of Kernataka valid till 30-10-2024		
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate issue din name of M/s Seraph Pharma dated 13-10-2023 for 100Kg of Etoricoxib along with Loan agreement for the drug substance between M/s Solaris Life Sciences and M/s Seraph Pharmaceuticals.		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Evaluation by PEC^{II}: Firm has initially submitted drug product stability studies data till 3rd month time point only.			
Decision: Registration Board approved the applications of Etoroxib 60mg tablets & Etoroxib 90mg tablets Furthermore, Registration Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			

➢ CLB in its 278th meeting held on 10 – 11 December, 2020 has approved grant of new DML, in name of M/s Nagarsons Pharmaceuticals Pvt Ltd. Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad including Capsuel general section.

345.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals Pvt Ltd. Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals Pvt Ltd. Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 165-3JU-MPX1 dated April 24th, 2024
	Details of fee submitted	Rs.30,000/- dated 19-03-2024
	The proposed proprietary name / brand name	**Dexnag 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains:

		Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole ……30mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Specification as per Innovator product

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 26-05-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Capsule general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Dextol 60MG DDR Capsule of M/s Seraph Pharmaceutical
Name and address of API manufacturer.	M/s. Vision Pharmaceuticals plot No 22-23 Industrial triangle Kahuta Road Islamabad
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the reference product Dexilant capsules.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	DLP987		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 capsules	1000 capsules	1000 capsules
Manufacturing Date	08-2023	08-2023	08-2023
No. of Batches	03		

346.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals Pvt Ltd. Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals Pvt Ltd. Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 14L-4M7-YV5B dated April 22nd, 2024
	Details of fee submitted	Rs.30,000/- dated 19-03-2024
	The proposed proprietary name / brand name	**Dexnag 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole ……60mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Specification as per Innovator product

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 26-05-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of grant of DML declaring grant of Capsule general Section also
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Dextol 60MG DDR Capsule of M/s Seraph Pharmaceutical
Name and address of API manufacturer.	M/s. Vision Pharmaceuticals plot No 22-23 Industrial triangle Kahuta Road Islamabad
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP studies of their product against the reference product Dexilant capsules.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	DLP987		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1000 capsules	1000 capsules	1000 capsules

Manufacturing Date	08-2023	08-2023	08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP, on basis of inspection conducted on 14-06-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice from M/s Vision Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC[II]:

Decision: Registration Board approved the applications of Dexnag 60mg Capsule & Dexnag 30mg Capsule.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- CLB in its 291st meeting held on 21-07-2023 has approved grant of additional sections including Eye Ointment Section, in name of M/s Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan

347.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: SV7-J2D-G5AS dated March 28th, 2024
	Details of fee submitted	Rs.30,000/- dated 05-03-2024
	The proposed proprietary name / brand name	**Fromore Ophthalmic Ointment**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of ointment contains: Fluorometholone. ……1mg (0.1%w/w)
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Section#	Observation	Firm's response

	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be provided since submitted reference product has been declared as Discontinued in US FDA without any declaration.	

Decision:

348.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: X53-RLR-45JT dated March 18th, 2024
	Details of fee submitted	Rs.30,000/- dated 05-03-2024
	The proposed proprietary name / brand name	**Optibram Ophthalmic Ointment**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of ointment contains: Tobramycin USP. ……3mg (0.3%w/w)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Section#	Observation	Firm's response
1.6.5	➢ Valid DML/GMP certificate of the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.	
2.3.R	➢ Complete batch manufacturing record of stability batches shall be submitted.	
3.2.S.4	➢ Drug substance specifications and analytical procedure shall be submitted from the drug substance manufacturer.	
3.2.S.4.3	➢ Clarification shall be submitted regarding the composition of placebo solution, applied for the performance of specificity parameter in analytical method verification studies.	
3.2.S.7.3	Long term stability studies data of drug substance shall be submitted till claimed shelf life.	
3.2.P.5.1	Justification shall be submitted for not incluing test of Antimicrobial/preservative effectiveness studies in drug product specifications as required by the USP general chapter <51>, since applied formulation contains preservative.	
3.2.P.5.3	➢ Sample preparation method applied for the performance of precision and recovery parameter in analytical method verification studies are not as recommended by the USP monograph. ➢ Detailed results shall be submitted along withdetails of blank and placebo solution preparation for the performance of specificity parameter.	

	➢ System suitability parameter performance is not as recommended by the USP monograph.	
3.2.P.6	COA of reference/working standard used for the analysis of the drug product stability batches shall be submitted since submitted COA declares expiry date prior to the manufacturing dates of the stability batches.	
3.2.P.8.3	• Sample and standard preparation as evident form the submitted raw data sheets as per USP monograph of Tobramycin Ointment, since it recommends use of Derivatized standard solution, Derivatized sample solution, and Blank solution while firm has used simple standad and sample solution. • Peak heights reported in the submitted chromatogrmas does not co-relate with the scale of the graph. • Systems suitability has not been perfomed as required by the USP monograph of Tobramycin Ointment. • Justification shall be submitted for not performing Antimicrobial/preservative effectiveness studies during stability studies, as required by the USP general chapter <51>, since applied formulation contains preservative.	

Decision: Deferred for submission of reply to above cited shortcomings.

➢ CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections including Suppository Section, in name of M/s Genix pharma (Pvt.) Ltd. 44, 45B, Korangi creek road, Karachi

349.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 9UT-P6P-P161 dated 19-1-2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 500mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response

1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

350.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: AVG-ZWT-RGQ5 dated 21-02-2024
	Details of fee submitted	Rs.75,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 1000mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 06-06-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.
Proposed Pack size	1's, 5's, 10's, 20's.
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by HPRA of Ireland
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	00510911/269/2023		
Description of Pack (Container closure system)	Aluminium foil		
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	23SB-498-01	23SB-499-02	23SB-500-03
Batch Size	100 suppositories	100 suppositories	100 suppositories
Manufacturing Date	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time stability studies and manual record for the accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units	

		• Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

351.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: V5H-ZTH-U3Y1 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 125mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

Evaluation by PECII:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH	

		• Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

352.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Z6Z-99G-7G47 dated 19-01-2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 250mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>:	We followed the testing specification as per USP monograph of"Acetaminophen Suppositories" and these tests

		• Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	are not mentioned in USP monograph. USP monograph is attached for your reference
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	Paracetamol Suppository is USP compliant product. The firm performed performance tests according to USP Monograph. However, the comparative analysis of both reference and applied product (Test product) had already submitted with its dossier.
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	• As per route of administration of suppositories. It melts at 37°C of body temperah1re and it is not possible to evaluate the accelerated study at 40°C so that's why we performed Accelerated study at 30°C and 65%RH and Real time study at 5°C ±°3c. USP monograph is attached in which storage condition is mentioned for your reference mentioned storage temperature. • The Criterion for fixation of batch size is based on the minimum requirements of samples being used for the stability analysis of products. • Selected batch size was sufficient enough for stability time points and to allow the process capability to establish and obtain quality product.

Decision: Registration Board approved the applications of KARMOL Suppository (500mg), KARMOL Suppository (1000mg), KARMOL Suppository (125mg) & KARMOL Suppository (250mg).

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

353.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 2VV-74X-2ZX1 dated 21-02-2024
	Details of fee submitted	Rs.75,000/- dated 31-01-2024
	The proposed proprietary name / brand name	**Tarol Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each suppository contains:** **Tramadol hydrochloride 100mg**
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	Innovator Specification
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
354.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: U6R-262-XTNH dated February 21st, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Mesazine Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Mesalazine …… 1000mg
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent (ATC code: A07EC02)
	Reference to Finished product specifications	BP Specification
355.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: PUU-VH7-DQ15 dated February 21st, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Mesazine Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Mesalazine …… 250mg

	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent (ATC code: A07EC02)
	Reference to Finished product specifications	BP Specification
356.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: VX6-J4P-MHYA dated February 13th, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Mesazine Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Mesalazine …… 500mg
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent (ATC code: A07EC02)
	Reference to Finished product specifications	BP Specification

Evaluation by PEC[II]:

Section#	Observations	Firm's responser
1.6.5	➢ Valid DML/GMP certificate of the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin..	Submitted

Decision: Registration Board approved the applications of Mesazine Suppository (1000mg), Mesazine Suppository (500mg) & Mesazine Suppository (250mg).

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

357.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 6MY-7ED-W9LQ dated February 16th, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Genart Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains Artesunate……. 100mg
	Pharmacotherapeutic Group of (API)	Anti-malarial Drug (ATC code: P01BE03)

	Reference to Finished product specifications	Innovator Specification
358.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: BLJ-VPE-2GDM dated February 23rd, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Genart Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains Artesunate……. 200mg
	Pharmacotherapeutic Group of (API)	Anti-malarial Drug (ATC code: P01BE03)
	Reference to Finished product specifications	Innovator Specification
359.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: ZMU-UXL-9NRH dated February 23rd, 2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Genart Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains Artesunate……. 50mg
	Pharmacotherapeutic Group of (API)	Anti-malarial Drug (ATC code: P01BE03)
	Reference to Finished product specifications	Innovator Specification

Evaluation by PEC[II]:

Section#	Observations	Firm's responser
1.5.9	Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting since submitted reference is of Soft gelatin capsule, while applied formulation is of suppository.	Artesunate suppository is widely available in many RRA countries recognized by DRAP. Health Canada recommends the use of Artesunate suppository for prevention and treatment of malaria. Artesunate suppository is also available in France by Medicale Pharmaceuticals, by Catalent (Eberbach, Germany) and packed and distributed by Scanpharm (Birkerod, Denmark). WHO is also the

		part of RRA, recognized and approved by DRAP. In February 2018, the first WHO-prequalified artesunate rectal suppository is available for the markets. It was developed against WHO recommended comparator product, manufactured by Catalent (Eberbach, Germany).
3.2.P.1	Clarification shall be submitted regarding applied formulation whether, soft gelatin capsule or suppository since cover letter and section 1.5.2 declares applied formulation as suppository while the composition, specifications and stability data submitted in module 3.2.P is for soft gelatin capsule.	The artesunate rectal dosage form, though appearing as a soft gelatin capsule, is unequivocally a suppository intended for rectal administration. Its formulation, design, and WHO prequalification status substantiate this classification, ensuring optimal therapeutic outcomes. This design aligns with the functional requirements of a rectal suppository, which is essential for effective treatment in scenarios where oral administration is not feasible. Despite its soft gelatin appearance, the product's formulation ensures it functions as a suppository. Rectal administration of artesw1ate is critical in managing severe malaria, especially in patients unable to take oral medications. The rectal route provides rapid absorption and onset of action, essential for treating life-threatening conditions.
3.2.P.2.2.1	Details of the innovator product against which CDP & PE studies are performed i.e. name of manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted with pictorial evidence.	We have performed PE against the Brand Artesunate Suppository ofM/s Cipla

Decision: Registration Board approved the applications of Genart suppository (100mg), Genart suppository (200mg) & Genart suppository (50mg)

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

360.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**

	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 7L5-ZN2-ZE3Y dated February 23rd, 2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Dimis Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Diclofenac Sodium …… 100mg
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drug (ATC code:M01AB05)
	Reference to Finished product specifications	Innovator Specification
361.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: XJ6-TT2-WB2A dated March 1st, 2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Dimis Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Diclofenac Sodium …… 50mg
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drug (ATC code:M01AB05)
	Reference to Finished product specifications	Innovator Specification
362.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: VTE-HU7-PL2D dated February 23rd, 202
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**Dimis Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Diclofenac Sodium …… 25mg
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drug (ATC code:M01AB05)
	Reference to Finished product specifications	Innovator Specification

Evaluation by PEC^{II}:
Decision: Registration Board approved the applications of Dimis suppository (100mg), Dimis suppository (50mg) & Dimis suppository (25mg) • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- M/s Safina Pharmaceutical (Pvt) Ltd., 17 km. Sheikhupura Road, Lahore has been re-Granted DML dated 10-06-2021 specifying Capsule (Cephalosprin) Section

363.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safina Pharmaceutical (Pvt) Ltd., 17 km. Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Safina Pharmaceutical (Pvt) Ltd., 17 km. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: ZX2-PMG-VUDA; February 20th, 2024
	Details of fee submitted	Rs.30,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**Sinocef Capsule 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephradine monohydrate equivalent to Cephradine…..500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
364.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safina Pharmaceutical (Pvt) Ltd., 17 km. Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Safina Pharmaceutical (Pvt) Ltd., 17 km. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 1LB-96D-PZX3; February 23rd, 2024
	Details of fee submitted	Rs.30,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**Sinocef Capsule 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephradine monohydrate equivalent to Cephradine…..250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Registration Board approved the applications of Sinocef Capsule 500mg & Sinocef Capsule 250mg. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

- CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections including Dry Powder Inhalation Section, in name of M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan

365.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: E58-TR8-D5LB; April 17th, 2024
	Details of fee submitted	Rs.75,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**Tresorol 100/62.5/25mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone furoate ……... 100 mcg Umeclidinium (as bromide) ……. 62.5 mcg Vilanterol (as trifenatate) …….25 mcg Each delivered dose contains: Fluticasone furoate…….....92 mcg Umeclidinium (as bromide) …….55 mcg Vilanterol (as trifenatate) ……. 22 mcg Accomapnying delivery device is “Roazon Inhaler device”.
	Pharmaceutical form of applied drug	DPI (Dry Powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD) depending on the product. Umeclidinium is a long-acting muscarinic antagonist and Vilanterol is a selective long-acting β2-agonist.
	Reference to Finished product specifications	As per Innovator’s Specifications.
366.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: LL5-6E7-LE8T; April 17th, 2024
	Details of fee submitted	Rs.75,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**Tresorol 200/62.5/25mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone furoate……...200 mcg Umeclidinium (as bromide) …….62.5 mcg

		Vilanterol (as trifenatate) …….25 mcg Each delivered dose contains: Fluticasone furoate……..….184 mcg Umeclidinium (as bromide) …….55 mcg Vilanterol (as trifenatate) …….22 mcg Accomapnying delivery device is "Roazon Inhaler device".
	Pharmaceutical form of applied drug	DPI (Dry Powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD) depending on the product. Umeclidinium is a long-acting muscarinic antagonist and Vilanterol is a selective long-acting β2-agonist.
	Reference to Finished product specifications	As per Innovator's Specifications.
Evaluation by PEC^{II}:		
Decision: Registration Board approved the applications of Tresorol 100/62.5/25mcg DPI Capsule & Tresorol 200/62.5/25mcg DPI Capsule. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Case no. 06 Registration applications of Human drugs applied on Form 5

CLB in its 270th meeting held on 23rd may, 2019 has considered & approved the grant of DML by the way of formulation with following 8 sections:
1. Tablet section (general)
2. Capsule section (general)
3. Sachet section (general)
4. Dry suspension section (general)
5. Cream and ointment (general) section
6. Oral liquid syrup/suspension(general) section
7. External application
8. Liquid repacking section.

Now the applicant has applied for following molecules/products against each section:

Extension in implementation timelines of SRO 713(I)/2018

The Authority in its 72nd meeting discussed regarding the "Extension in implementation timelines of SRO 713(I)/2018 and decided as follows:-
1. Allowed those companies, for which panel for inspection has been constituted before 07-03-2019, to submit registration applications on Form 5 instead of Form 5F for initial 10 molecules per section only.
2. The exemption will remain valid till 31-12-2019.
3. No further exemption will be granted in any case.
4. Inspectors / panel members are advised to formally report every visit. Concerned Division were advised to specify a timeline for conducting/ concluding panel inspection.

a) Details of issuance of DML are as follow:

Name of Firm	Date of issuance of panel inspection letter	Date of issuance of DML	Date of Submission of applications
M/s Healthcare Pharmaceuticals Multan	31st January 2019	28th June 2019	November and December 2019

The submission of following applications on foirm-5 are in line with the decision of Authority

367.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Betacare-S Lotion**
	Composition	Each ml Contains: Betamethasone as dipropionate…0.5mg Salicylic Acid…20mg
	Diary No. Date of R& I & fee	Dy.No 28331 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form -5
	Finished product Specification	Manfacturer's
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diprosalic Scalp Application 0.05% w/w / 2% w/w, cutaneous solution approved by MHRA of UK
	Me-too status	Provate-S Lotion of M.s Saffron
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
368.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Conazole 2% Lotion**
	Composition	Each ml Contains: Ketoconazole…2%
	Diary No. Date of R& I & fee	Dy.No 28327 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Antifungal
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dandrazol 2 % Topical Solution Transdermal Limited, Merlin House, Brunel Road, Theale, Reading,RG 7 4 AB **(MHRA)**
	Me-too status	Ketocal Lotion by M/s Caliph Pharma
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved.	
369.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Scarbin 5% Lotion**
	Composition	Each ml Contains: Permethrin…5%w/v

	Diary No. Date of R& I & fee	Dy.No 28328 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Type of Form	Form -5
	Finished product Specification	Manfacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Permethrin 5 % w/v Lotion M/s GSK (MHRA Approved)
	Me-too status	Plaveo Lotion by M/s Hiranis Pharmaceuticals (Reg.#76508)
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
370.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Sakoon Emulsion**
	Composition	Each 5ml Contains: Benzyl Benzoate…25%
	Diary No. Date of R& I & fee	Dy.No 28332 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Anti scabies
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	Benzil Emulsion 25% (Reg#054616)
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	Evidence of approval of applied formulation by reference regulatory authority is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
371.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Clinda 1% Lotion**
	Composition	Each ml Contains: Clindamycin as phosphate…1%w/v
	Diary No. Date of R& I & fee	Dy.No 28326 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Lincomycin Antibiotics
	Type of Form	Form -5
	Finished product Specification	USP Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Acsolve Lotion by M/s Atco Pharma
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved.	
372.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**

	Brand Name +Dosage Form + Strength	**Momesone 0.1% Lotion**
	Composition	Each ml Contains: Mometasone Furoate…0.1%w/v
	Diary No. Date of R& I & fee	Dy.No 28335 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Anti-inflammatory, Antipruritic
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MOMETASONE-ZP mometasone furoate 0.1% w/w lotion bottle by M/s Medis Pharma Pty Ltd, TGA Australia Aprroved.
	Me-too status	Acsolve Lotion by M/s Atco Pharma
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved.	
373.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Sodacare Drop**
	Composition	Each 100ml Contains: Sodium Bicarbonate…% Glycerin…30%
	Diary No. Date of R& I & fee	Dy.No 28333 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	--
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	Soda Glycerin Ear Drops of M/s Prime Laboratories (Reg.# 28622)
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	Evidence of approval of applied formulation by reference regulatory authority is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
374.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Terbina 1% Lotion**
	Composition	Each ml Contains: Terbinafine HCl…..…10mg
	Diary No. Date of R& I & fee	Dy.No 28324 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Antifungal Agents
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil Lotion 1% by M/s GSK of Netherland approved
	Me-too status	Cutis Lotion of M/s Tabros Pharma Reg# 067109

	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
375.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Sulmiton Forte Lotion**
	Composition	Each ml Contains: Crotamiton…10% Sulphur…5%
	Diary No. Date of R& I & fee	Dy.No 28330 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Scabicide
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	Scabion forte Lotion of M.s Atco
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
376.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Payocare Surgical Scrub**
	Composition	Each ml Contains: Povidone-Iodine 75mg Eq. To 7.5 available Iodine
	Diary No. Date of R& I & fee	Dy.No 28336 dated 27-12-2019 Rs.20,000/- dated 26-12-2019
	Pharmacological Group	Antiseptic, germicidal
	Type of Form	Form -5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	C-Pyidine Scrub Care 7.5 by Cortex Pharma
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	•
	Decision: Approved.	
377.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Payocare Solution**
	Composition	Each 1ml Contains: - Povidone Iodine 100mg equivalent to available Iodine ……. 10 mg
	Diary No. Date of R& I & fee	Dy.No 28337 dated 27-12-2019 Rs.20,000/- dated 26-12-2019

	Pharmacological Group	Antiseptic, germicidal
	Type of Form	Form -5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Pyodine 10% Solution by Brookes Pharma
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	•
	Decision: Approved.	
378.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Sulmiton Lotion**
	Composition	Each ml Contains: Crotamiton…10% Sulphur…2%
	Diary No. Date of R& I & fee	Dy.No 28329 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Scabicide
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	Scabion Lotion of M.s Atco
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
379.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Payocare Gargle & Mouth Wash**
	Composition	Each 100ml Contains: Povidone-Iodine 10G Eq. To 0.10 Available Iodine
	Diary No. Date of R& I & fee	Dy.No 28338 dated 27-12-2019 Rs.20,000/- dated 26-12-2019
	Pharmacological Group	Antiseptic, germicidal
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	--
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
380.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Lactocare Syrup**
	Composition	Each 5ml Contains: Lactulose…3.35G
	Diary No. Date of R& I & fee	Dy.No 28335 dated 27-12-2019 Rs.20,000/- dated 26-12-2019
	Pharmacological Group	Laxative
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Importal Syrup by M/s Novartis (Swissmedica)
	Me-too status	Lacasil 10g/15ml syrup by M/s Sami Pharmaceuticals Pvt. Limited. (Reg#070552)
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approvd. Firm shal submit sdocumenst for othe source of Lactulose along with fee in case of bulk import	
381.	**Name and address of manufacturer / Applicant**	**M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan**
	Brand Name +Dosage Form + Strength	**Ferocare 50mg/ml Drops**
	Composition	Each 1ml Contains: Iron Polymaltose Complex Eq. To Elemental Iron…50mg
	Diary No. Date of R& I & fee	Dy.No 28334 dated 27-12-2019 Rs.20,000/- dated 26-12-2019
	Pharmacological Group	Iron Supplement (Iron Prepartion)
	Type of Form	Form -5
	Finished product Specification	Manufacturr's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MALTOFER DROPS by Vifor Pharma Pty Ltd, TGA Approved.
	Me-too status	RubiferOral Drops 50mg/ml by M/s AGP Pvt. .Ltd., Reg# 031051
	GMP status	DML granted on basis of inspection conducted on 31st January 2019.
	Evaluation by PEC	
	Decision: Approved.	

382.	**Name and address of manufacturer / Applicant**	M/s Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Lahore **contract manufacturing by** M/s GMP pharmaceutical, 28-KM, Sheikhpura Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	**Cefizet 400mg Capsule**
	Composition	Each capsule Contains: Cefixime as trihydrate…400mg

	Diary No. Date of R& I & fee	Dy.No 15061 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specification	Manufacturer specifictions
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefixime 400mg capsule **(MHRA** Approved)
	Me-too status	Cefim Capsule by Hilton
	GMP status	
	Evaluation by PEC	
	Decision: Approved as per manufacturer's specifications notified vide Notification no. F.14-1/2022-PEC dated 14-03-2022.	
383.	**Name and address of manufacturer / Applicant**	M/s Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Lahore **contract manufacturing by** M/s GMP pharmaceutical, 28-KM, Sheikhpura Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	**Cefizet 200mg Susp**
	Composition	Each 5ml Contains: Cefixime as trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 15063 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SUPRAX 200mg/5ml Dry Powder Suspension Lupin Ltd. USFDA Approved
	Me-too status	Rofixime DS Suspension by SPL Pharmaceuticals (Pvt) Ltd, (Reg#45506)
	GMP status	
	Evaluation by PEC	
	Decision: Approved as per manufacturer's specifications notified vide Notification no. F.14-1/2022-PEC dated 14-03-2022.	
384.	**Name and address of manufacturer / Applicant**	M/s Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Lahore **contract manufacturing by** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	**Zectum Injectin 2gm**
	Composition	Each Vial Contains: Cefoperazone Sodium Eq. to Cefoperazone…1g Sulbactam Sodium Eq. to Sulbactam…1g
	Diary No. Date of R& I & fee	Dy.No 15065 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Bulgaria: Sulcef 1g/1g powder for solution for injection Lithuania: Sulcef 1g/1g powder for solution for injection Slovakia: Sulcef 2g powder for solution for injection
	Me-too status	2Sum injection by Sami

	GMP status	Firm has submitted copy of GMP certificate of M/s MTI dated 25.05.2023 by DRAP Lahore based on inspection conducted on 31.01.2023.
	Evaluation by PEC	
	Decision: Approved.	

Case no. 07 Registration applications applied on Form 5/5D after 07th March, 2019.

Following cases have been applied on Form 5/5D after the cut off date of 07th March, 2019, instead of applying on prescribed form for submission of registration applications of Human Drugs i.e., Form 5F under Drugs (Licensing, Registering & Advertising) Rules, 1976. Submitted for consideration of Board please.

Sr.#	Name and Address of Manufacturer	Brand Name	Composition	Type of Form, Diary No and Date of Submission, Deposited Fee and Date
1.	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore	Empaglu Tablet 25mg	Each Film Coated Tablet Contains: Empagliflozin…25mg	Form-5 Dy.No 2144 dated 11-03-2019 Rs.20,000/- dated 11-03-2019
2.	M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore	Daclocef 125mg/5ml Suspension	Each 5ml Suspension Contains: Cephradine…125mg	Form-5 Dy.No 808 dated 15-03-2019 Rs.20,000/- dated 14-03-2019
3.	M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore	Daclocef 250mg/5ml Suspension	Each 5ml Suspension Contains: Cephradine…250mg	Form-5 Dy.No 809 dated 15-03-2019 Rs.20,000/- dated 14-03-2019
4.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Pantas-IT Capsule	Each Delayed Release Capsule Contains: Pantoprazole As Sodium…40mg Itopride Hcl…150mg	Form-5 Dy.No 1111 dated 18-03-2019 Rs.20,000/- dated 18-03-2019
5.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Histab 16mg Tablet	Each Tablet Contains: Betahistine Dihydrochloride…16mg	Form-5 Dy.No 966 dated 18-03-2019 Rs.50,000/- dated 18-03-2019
6.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Empaglu Tablet 12.5/1000mg	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg	Form-5 Dy.No 965 dated 18-03-2019 Rs.20,000/- dated 18-03-2019
7.	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore	Anapan Tablets 250mg	Each Tablet Contains: Mefenamic Acid…250mg	Form-5 Dy.No 2122 dated 29-03-2019 Rs.20,000/- dated 27-03-2019
8.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	MBC 200mg Tablet	Each Film Coated Tablet Contains: Mebeverine Hcl…200mg	Form-5 Dy.No 2516 dated 03-04-2019 Rs.20,000/- dated 31-01-2019
9.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Tofanib XR Tablets 11mg	Each Extended Release Tablet Contains: Tofacitinib As Citrate…11mg	Form-5D Dy.No 3806 dated 08-04-

				2019 Rs.50,000/- dated 17-04-2019
385.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Adrance M XR Tablets 10mg/1000mg	Each Tablet Contains: Empagliflozin…10mg Metformin Hcl (Extended Releases)…1000mg	Form-5D Dy.No 3816 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
386.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Delameg Tablets 450mg	Each Tablet Contains: Delafloxacin As Delafloxacin Meglumine…450mg	Form-5D Dy.No 3804 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
387.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Itonaz Capsule 100mg	Each Capsule Contains: Itraconazole…100mg	Form-5 Dy.No 3814 dated 08-04-2019 Rs.20,000/- dated 17-04-2019
388.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Itonaz Tablet 200mg	Each Film Coated Tablet Contains: Itraconazole…200mg	Form-5D Dy.No 3814 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
389.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Adrance M XR Tablets 5mg/1000mg	Each Tablet Contains: Empagliflozin…5mg Metformin Hcl (Extended Releases)…1000mg	Form-5D Dy.No 3815 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
390.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Aprem Tablet 30mg	Each Film Coated Tablet Contains: Apremilast…30mg	Form-5D Dy.No 3811 dated 08-04-2019 Rs.50,000/- dated 17-04-2019 Also Applied on Form 5-F
391.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Bynevol H Tablets 5mg/12.5mg	Each Film Coated Tablet Contains: Nebivolol Hcl…5mg Hydrochloride…12.5mg	Form-5D Dy.No 3807 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
392.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Bynevol H Tablets 5mg/25mg	Each Film Coated Tablet Contains: Nebivolol Hcl…5mg Hydrochloride…25mg	Form-5D Dy.No 3808 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
393.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Tofanib Tablets 5mg	Each Film Coated Tablet Contains: Tofacitinib As Citrate…5mg	Form-5D Dy.No 3805 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
394.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Adrance M XR Tablets 25mg/1000mg	Each Tablet Contains: Empagliflozin…25mg Metformin Hcl (Extended Releases)…1000mg	Form-5D Dy.No 3818 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
395.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Itonaz OS Oral Solution	Each ml Contains: Itraconazole…10mg	Form-5D Dy.No 3812 dated 08-04-2019 Rs.50,000/- dated 17-04-2019

396.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Aprem Tablet 10mg	Each Film Coated Tablet Contains: Apremilast…10mg	Form-5D Dy.No 3809 dated 08-04-2019 Rs.50,000/- dated 17-04-2019 Also Applied on Form 5-F
397.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Aprem Tablet 20mg	Each Film Coated Tablet Contains: Apremilast…20mg	Form-5D Dy.No 3810 dated 08-04-2019 Rs.50,000/- dated 17-04-2019 Also Applied on Form 5-F
398.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Adrance M XR Tablets 12.5mg/1000mg	Each Tablet Contains: Empagliflozin…12.5mg Metformin Hcl (Extended Releases)…1000mg	Form-5D Dy.No 3817 dated 08-04-2019 Rs.50,000/- dated 17-04-2019
399.	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	Dorip Injection 250mg	Each Vial Contains: Doripenem…250mg	Form-5 Dy.No 4505 dated 25-04-2019 Rs.20,000/- dated 24-04-2019
400.	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	Dorip Injection 500mg	Each Vial Contains: Doripenem…500mg	Form-5 Dy.No 4506 dated 25-04-2019 Rs.20,000/- dated 24-04-2019
401.	M/s Medicaids Pakistan (pvt) Ltd. Plot No 10, Sector-27 Korangi Industrial Area, Karachi	Melor 8mg Tablet	Each Tablet Contains: Lornoxicam…8mg	Form-5 Dy.No 9662 dated 03-05-2019 Rs.20,000/- dated 03-05-2019
402.	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore	Ferista 100mg/ml Injection	Each 1ml Ampoule Contains: Iron As Iron Iii Isomaltoside 1000…100mg	Form-5 Dy.No 6063 dated 14-05-2019 Rs.20,000/- dated 14-05-2019
403.	M/s Meditech Pharmaceuticals. 15-D, Industrial Estate, Hayatabad, Peshawar, Pakistan By M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Meroteck 1gm Injection	Each Vial Contains: Meropenem As Trihydrate…1gm	Form-5 Dy.No 7660 dated 30-05-2019 Rs.50,000/- dated 30-05-2019
404.	M/s Meditech Pharmaceuticals. 15-D, Industrial Estate, Hayatabad, Peshawar, Pakistan By M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Meroteck 500mg Injection	Each Vial Contains: Meropenem As Trihydrate…500mg	Form-5 Dy.No 7659 dated 30-05-2019 Rs.50,000/- dated 30-05-2019

405.	M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar By M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Razapem 500mg Injection	Each Vial Contains: Meropenem As Trihydrate…500mg	Form-5 Dy.No 7657 dated 30-05-2019 Rs.50,000/- dated 30-05-2019
406.	M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar By M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Razapem 1gm Injection	Each Vial Contains: Meropenem As Trihydrate…1gm	Form-5 Dy.No 7658 dated 30-05-2019 Rs.50,000/- dated 30-05-2019
407.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi By M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore	Promest 25mg Tablet	Each Gram Contains: Mesterolone…25mg	Form-5 Dy.No 7938 dated 10-06-2019 Rs.50,000/- dated 10-06-2019
408.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi By M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore	Accure 0.035mg/2mg Tablet	Each Gram Contains: Ethinylestradiol…0.035mg Cyproterone Acetate…2mg	Form-5 Dy.No 7935 dated 10-06-2019 Rs.50,000/- dated 10-06-2019
409.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi By M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore	Gynor 5mg Tablet	Each Gram Contains: Norethisterone…5mg	Form-5 Dy.No 7937 dated 10-06-2019 Rs.50,000/- dated 10-06-2019
410.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi By M/s Pharma Health Pakistan Pvt Ltd.	Androne 250mg/ml Injection	Each ml Contains: Testosterone Enanthate…250mg	Form-5 Dy.No 7936 dated 10-06-2019 Rs.50,000/- dated 10-06-2019

	17-Km, Ferozepur Road, Lahore			
411.	M/s Elite Pharma (Pvt) Ltd. P.D.H. St. 9.5 KM Sheikhupura Road, Lahore	Elicurium 10mg/ml	Each ml Contains: Atracurium Besylate…10mg	Form-5 Dy.No 8531 dated 17-06-2019 Rs.20,000/- dated 17-06-2019
412.	M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi	Olodin Opthalmic solution 0.2%	Each ml Contains: Olopatadine…0.2%	Form-5 Dy.No 9084 dated 20-06-2019 Rs.20,000/- dated 19-06-2019
413.	M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi	Aqua Plus Opthalmic Solution	Each ml Contains: Polyethylene Gluconol…400-0.4% Propylene Glycol…0.3%	Form-5 Dy.No 9083 dated 20-06-2019 Rs.20,000/- dated 19-06-2019
414.	M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi	Nepax Opthalmic solution 0.1%	Each ml Contains: Nepafenac…0.1%	Form-5 Dy.No 9080 dated 20-06-2019 Rs.20,000/- dated 19-06-2019
415.	M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi	Lotemax Opthalmic solution 0.5/0.3%	Each ml Contains: Loteprednol Etabonate…0.5% Tobramycin…0.3%	Form-5 Dy.No 9081 dated 20-06-2019 Rs.20,000/- dated 19-06-2019
416.	M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi	Dorzol Opthalmic solution 2/0.5%	Each ml Contains: Dorzolamide…2% Timolol…0.5%	Form-5 Dy.No 9082 dated 20-06-2019 Rs.20,000/- dated 19-06-2019
417.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi By M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Tazolinz 4.5g Injection	Each Vial Contains: Sterile Piperacillin Sodium Eq. To Piperacillin…4G Sterile Tazobactam Sodium Eq. To Tazobactam…0.5G	Form-5 Dy.No 9753 dated 26-06-2019 Rs.50,000/- dated 26-06-2019
418.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi By M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector	Tazolinz 3.375g Injection	Each Vial Contains: Sterile Piperacillin Sodium Eq. To Piperacillin…3G Sterile Tazobactam Sodium Eq. To Tazobactam…0.375G	Form-5 Dy.No 9752 dated 26-06-2019 Rs.50,000/- dated 26-06-2019

	23, Korangi Industrial Area, Karachi, Pakistan			
419.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi By M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Tazolinz 2.25g Injection	Each Vial Contains: Sterile Piperacillin Sodium Eq. To Piperacillin…2G Sterile Tazobactam Sodium Eq. To Tazobactam…0.25G	Form-5 Dy.No 9751 dated 26-06-2019 Rs.50,000/- dated 26-06-2019
420.	M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Imiclast 250mg Injection	Each Vial Contains: Imipenem As Monohydrate…250mg Cilastatin As Sodium…250mg	Form-5 Dy.No 7655 dated 30-05-2019 Rs.20,000/- dated 30-05-2019
421.	M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Ertacraft 1gm Injection	Each Vial Contains: Ertapenem As Sodium…1gm	Form-5 Dy.No 7652 dated 30-05-2019 Rs.20,000/- dated 30-05-2019
422.	M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan	Imiclast 500mg Injection	Each Vial Contains: Imipenem As Monohydrate…500mg Cilastatin As Sodium…500mg	Form-5 Dy.No 7656 dated 30-05-2019 Rs.20,000/- dated 30-05-2019
423.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Mykast 10mg Tablet	Each Film Coated Tablet Contains: Montelukast Sodium…10mg	Form-5 Dy.No 18145 dated 20-09-2019 Rs.20,000/- dated 17-09-2019
424.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Mykast 5mg Tablet	Each Film Coated Tablet Contains: Montelukast Sodium…5mg	Form-5 Dy.No 18146 dated 20-09-2019 Rs.20,000/- dated 17-09-2019
425.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Lenox 500mg Tablet	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate Eq. To Levofloxacin…500mg	Form-5 Dy.No 18144 dated 20-09-2019 Rs.20,000/- dated 17-09-2019
426.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Lenox 750mg Tablet	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate Eq. To Levofloxacin…750mg	Form-5 Dy.No 18143 dated 20-09-2019 Rs.20,000/- dated 17-09-2019
427.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Racedo 10mg Granules	Each Sachet Contains: Racecadotril…10mg	Form-5 Dy.No 22268 dated 29-10-2019 Rs.20,000/- dated 29-10-2019

428.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Racedo 30mg Granules	Each Sachet Contains: Racecadotril…30mg	Form-5 Dy.No 22267 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
429.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Sacu-V 24/26 mg Tablet	Each Film Coated Tablet Contains: Sacubitril…24.3mg Valsartan…25.7mg (As Sacubitril Valsartan Sodium Salt Complex)	Form-5 Dy.No 22257 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
430.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Escital 10mg Tablet	Each Orodispersible Tablet Contains: Escitalopram…10mg As Escitalopram Base	Form-5 Dy.No 22258 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
431.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Salzine 1gm Prolonged Release Granules	Each Sachet Contains: Mesalazine…1gm	Form-5 Dy.No 22266 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
432.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin 100mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 102mg Eq. To Canagliflozin…100mg	Form-5 Dy.No 22265 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
433.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin 300mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 306mg Eq. To Canagliflozin…300mg	Form-5 Dy.No 22264 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
434.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Sacu-V 49/51 mg Tablet	Each Film Coated Tablet Contains: Sacubitril…48.6mg Valsartan…51.4mg (As Sacubitril Valsartan Sodium Salt Complex)	Form-5 Dy.No 22256 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
435.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Sacu-V 97/103 mg Tablet	Each Film Coated Tablet Contains: Sacubitril…97.2mg Valsartan…102.8mg (As Sacubitril Valsartan Sodium Salt Complex)	Form-5 Dy.No 22255 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
436.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin-M 150mg/1000mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 153mg Eq. To Canagliflozin…150mg Metformin Hcl…1000mg	Form-5 Dy.No 22260 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
437.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin-M 50mg/1000mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 51mg Eq. To Canagliflozin…50mg Metformin Hcl…1000mg	Form-5 Dy.No 22262 dated 29-10-2019 Rs.20,000/- dated 29-10-2019

438.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin-M 150mg/500mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 53mg Eq. To Canagliflozin…150mg Metformin Hcl…500mg	Form-5 Dy.No 22261 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
439.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Canazin-M 50mg/500mg Tablet	Each Film Coated Tablet Contains: Canagliflozin Hemihydrate 51mg Eq. To Canagliflozin…50mg Metformin Hcl…500mg	Form-5 Dy.No 22263 dated 29-10-2019 Rs.20,000/- dated 29-10-2019
440.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Boschoflu 1000mg/10mg Powder For Oral Solution	Each Sachet Contains: Paracetamol…1000mg Phenylephirine Hcl 12.2mg Eq. To Phenylephirine…10mg	Form-5D Dy.No 22259 dated 29-10-2019 Rs.50,000/- dated 29-10-2019
441.	M/s Elite Pharma (Pvt) Ltd. P.D.H. St. 9.5 KM Sheikhupura Road, Lahore	Ketomine 30mg/ml Injection	Each ml Contains: Ketorolac Tromethamine…30mg	Form-5 Dy.No 23388 dated 11-11-2019 Rs.20,000/- dated 11-11-2019
442.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Derma Soft Solution	Each ml Of Solution Contains: Fluocinolone Acetonide…0.1mg	Form-5 Dy.No 24732 dated 22-11-2019 Rs.20,000/- dated 22-11-2019
443.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Clozole Cream	Each Gram Of Cream Contains: Clotrimazole And Hydrocortisone Acetate Eq. To 10mg Hydrocortisone	Form-5 Dy.No 24958 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
444.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Amrokort 0.1% w/w Ointment	Each Gram Contains: Triamcinolone Acetonide…1mg	Form-5 Dy.No 24959 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
445.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	PS-Dar Syrup	Each Tablet Contains: Pyrimethamine…25mg Sulfadoxine…500mg	Form-5 Dy.No 24960 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
446.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Amvinate 50mg Tablet	Each Tablet Contains: Dimenhydrinate…50mg	Form-5 Dy.No 24957 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
447.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Vaginal 10% w/w Cream	Each Gram Contains: Clotrimazole…100mg	Form-5 Dy.No 24964 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
448.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	V-Vaginal 100mg Tablet	Each Tablet Contains: Clotrimazole…100mg	Form-5 Dy.No 24965 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
449.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	V-Vaginal 500mg Tablet	Each Tablet Contains: Clotrimazole…500mg	Form-5 Dy.No 24966 dated 25-11-2019 Rs.20,000/- dated 25-11-2019

450.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mospa Forte 80mg Tablet	Each Tablet Contains: Drotaverine Hcl…80mg	Form-5 Dy.No 24961 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
451.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mospa 40mg Tablet	Each Tablet Contains: Drotaverine Hcl…40mg	Form-5 Dy.No 24962 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
452.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mospa 40mg/2ml Injection	Each 2ml Contains: Drotaverine Hcl…40mg	Form-5 Dy.No 24963 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
453.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Ambol Syrup	Each 5ml Contains: Pyritinol Hcl…80.5mg	Form-5 Dy.No 25111 dated 26-11-2019 Rs.20,000/- dated 26-11-2019
454.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Ambol 100mg Tablet	Each Film Coated Tablet Contains: Pyritinol Hcl…100mg	Form-5 Dy.No 25110 dated 26-11-2019 Rs.20,000/- dated 26-11-2019
455.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Gradex 30mg Capsule	Each Capsule Contains: Enteric Coated Pellets Of Dexlansoprazole Eq. To Dexlansoprazole…30mg	Form-5 Dy.No 25481 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
456.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Gradex 60mg Capsule	Each Capsule Contains: Enteric Coated Pellets Of Dexlansoprazole Eq. To Dexlansoprazole…60mg	Form-5 Dy.No 25482 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
457.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	G-Zole 40mg Capsule	Each Capsule Contains: Omeprazole As Enteric Coated Pellets Eq. To Omperazole…40mg	Form-5 Dy.No 25480 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
458.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	G-Zole 20mg Capsule	Each Capsule Contains: Omeprazole As Enteric Coated Pellets Eq. To Omperazole…20mg	Form-5 Dy.No 25479 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
459.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Diloner 30mg Capsule	Each Capsule Contains: Duloxetine Enteric Coated Pellets 17% Eq. To Duloxetine…30mg	Form-5 Dy.No 25478 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
460.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Premac 75mg Capsule	Each Capsule Contains: Pregabalin…75mg	Form-5 Dy.No 25477 dated 29-11-2019 Rs.20,000/- dated 29-11-2019
461.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Clariskin Cream	Each Gram Of Tube Contains: Hydroquinone…40mg	Form-5 Dy.No 25896 dated 03-12-2019 Rs.20,000/- dated 03-12-2019

462.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Premac 75mg Capsule	Each Capsule Contains: Pregabalin…75mg	Form-5 Dy.No 25897 dated 03-12-2019 Rs.20,000/- dated 03-12-2019
463.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Gratasone 0.1% Lotion	Each Gram Of Lotion Contains: Mometasone Furoate…1mg	Form-5 Dy.No 25895 dated 03-12-2019 Rs.20,000/- dated 03-12-2019
464.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Esdu 20mg Capsule	Each Capsule Contains: Esomeprazole…20mg	Form-5 Dy.No 25899 dated 03-12-2019 Rs.20,000/- dated 03-12-2019
465.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	G-Mith 5% Lotion	Each Gram Of Lotion Contains: Permethrin…50mg	Form-5 Dy.No 25898 dated 03-12-2019 Rs.20,000/- dated 03-12-2019
466.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Calox 15/5 % Lotion	Each ml Of Lotion Contains: Calamine…150mg Zinc Oxide…50mg	Form-5 Dy.No 26010 dated 04-12-2019 Rs.20,000/- dated 04-12-2019
467.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Gratovate 0.05% Lotion	Each ml Of Lotion Contains: Fluticasone Propionate…0.5mg	Form-5 Dy.No 26655 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
468.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Topica 0.25% Lotion	Each Gram Of Lotion Contains: Prednicarbate…2.5mg	Form-5 Dy.No 26654 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
469.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Hy-Zole Cream	Each gm Of Solution Contains: Fluocinolone Acetonide…0.1mg	Form-5 Dy.No 26653 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
470.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Beta-C Ointment	Each Gram Of Ointment Contains: 52.18Mcg Of Calcipotriol Hydrate (Eq. To 50Mcg Of Calcipotriene) 0.643mg Of Betamethasone Dipropionate (Eq. To 0.5mg Of Betamethasone	Form-5 Dy.No 26652 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
471.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	B-Clot Lotion	Each Gram Of Lotion Contains: Clotrimazole…10mg Betamethasone Dipropionate Eq. To Betamethasone…0.5mg	Form-5 Dy.No 26656 dated 10-12-2019 Rs.20,000/- dated 10-12-2019

472.	M/s Greater Pharma. Plot No. 35, Street No. SS-3, National Industrial Zone RCCI, Rawat, Islamabad, Pakistan	Halop 0.01% Lotion	Each Gram Of Lotion Contains: Halobetasol Propionate…0.1mg	Form-5 Dy.No 26651 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
473.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palphine 10mg/ml Injection	Each 1ml Ampoule Contains: Nalbuphine Hcl…10mg	Form-5 Dy.No 26649 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
474.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palphine 20mg/ml Injection	Each 1ml Ampoule Contains: Nalbuphine Hcl…20mg	Form-5 Dy.No 26650 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
475.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	TP-Dol 37.5/325 mg Tablet	Each Tablet Contains: Tramadol Hcl…37.5mg Paracetamol…325mg	Form-5 Dy.No 26644 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
476.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Ketopal 30mg/ml Injection	Each 1ml Ampoule Contains: Ketorolac Tromethamine…30mg	Form-5 Dy.No 26646 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
477.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Moxipal 400mg Tablet	Each Film Coated Tablet Contains: Moxifloxacin As Hcl…400mg	Form-5 Dy.No 26645 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
478.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Moxipal 400mg/250ml Infusion	Each 250ml Vial Contains: Moxifloxacin…400mg	Form-5 Dy.No 26648 dated 10-12-2019 Rs.20,000/- dated 10-12-2019
479.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palrox 20mg Tablet	Each Film Coated Tablet Contains: Paroxetine As Hcl…20mg	Form-5 Dy.No 27524 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
480.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palfipime 1g Injection	Each Vial Contains: Cefepime As Hcl With L-Arginine…1gm	Form-5 Dy.No 27523 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
481.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Paleram 20mg Tablet	Each Film Coated Tablet Contains: Escitalopram As Oxalate…10mg	Form-5 Dy.No 27526 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
482.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Paleram 10mg Tablet	Each Film Coated Tablet Contains: Escitalopram As Oxalate…10mg	Form-5 Dy.No 27525 dated 19-12-2019 Rs.20,000/- dated 19-12-2019

483.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Olanpex 10mg Tablet	Each Film Coated Tablet Contains: Olanzapine…10mg	Form-5 Dy.No 27528 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
484.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Olanpex 5mg Tablet	Each Film Coated Tablet Contains: Olanzapine…5mg	Form-5 Dy.No 27527 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
485.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palzon 2g Injection	Each Vial Contains: Ceftriaxone As Sodium…2gm	Form-5 Dy.No 27522 dated 19-12-2019 Rs.20,000/- dated 19-12-2019
486.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Emin 400mg Capsule	Each Capsule Contains: Vitamin E…400mg	Form-5 Dy.No 29229 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
487.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Oragel-D 50000 IU Capsule	Each Soft Gelatin Capsule Contains: Cholecalciferol (Vitamin D3)…50000 Iu	Form-5 Dy.No 29237 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
488.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Calitrol 0.25mcg Capsule	Each Soft Capsule Contains: Calcitriol…0.25Mcg	Form-5 Dy.No 29225 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
489.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Adecol 295mg Capsule	Each Soft Gelatin Capsule Contains: Cod Liver Oil…295mg Eq. To Vitamin A…600 Iu Vitamin D…60 Iu Vitamin E…0.2mg	Form-5 Dy.No 29224 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
490.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Emin 600mg Capsule	Each Capsule Contains: Vitamin E…600mg	Form-5 Dy.No 29230 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
491.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Duta 0.5mg Capsule	Each Capsule Contains: Dutasteride…0.5mg	Form-5 Dy.No 29227 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
492.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Calitrol 0.5mcg Capsule	Each Soft Capsule Contains: Calcitriol…0.5Mcg	Form-5 Dy.No 29226 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
493.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Itret 20mg Capsule	Each Soft Gelatin Capsule Contains: Isotretinoin…20mg	Form-5 Dy.No 29232 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
494.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Itret 10mg Capsule	Each Soft Gelatin Capsule Contains: Isotretinoin…10mg	Form-5 Dy.No 29231 dated 03-01-2020 Rs.20,000/- dated 01-01-2020

495.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Oragel-D 20000 IU Capsule	Each Soft Gelatin Capsule Contains: Cholecalciferol (Vitamin D3)…20000 Iu	Form-5 Dy.No 29236 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
496.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Immunax Soft 100mg Capsule	Each Soft Capsule Contains: Cyclosporine…100mg	Form-5 Dy.No 29235 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
497.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Immunax Soft 50mg Capsule	Each Soft Capsule Contains: Cyclosporine…50mg	Form-5 Dy.No 29234 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
498.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Immunax Soft 25mg Capsule	Each Soft Capsule Contains: Cyclosporine…25mg	Form-5 Dy.No 29233 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
499.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Emin 200mg Capsule	Each Capsule Contains: Vitamin E…200mg	Form-5 Dy.No 29228 dated 03-01-2020 Rs.20,000/- dated 01-01-2020
500.	M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Levox 250mg Tablet	Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	Form-5 Dy.No 24114 dated 16-09-2020 Rs.20,000/- dated 16-09-2020
501.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Pulmaid 62.5mg Tablet	Each Film Coated Tablet Contains: Bosentan as Monohydrate…62.5mg	Form-5 Dy.No 29064 dated 18-12-2023 Rs 30,000/- dated 15-12-2023
502.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Pulmaid Forte 125mg Tablet	Each Film Coated Tablet Contains: Bosentan as Monohydrate…125mg	Form-5 Dy.No 29065 dated 18-12-2023 Rs 30,000/- dated 15-12-2023

Decision: Registration Board noted the fact that cut off date for submission of registration applications of Human Drugs on Fomr 5, 5D or 5A was 07th March, 2019 and thereafter the prescribed form for submission of registration applications of Human Drugs is Form 5F, as per Drugs (Licensing, Registering & Advertising) Rules, 1976. Since the above presented applications have not been submitted on prescribed Form 5F as per Drugs (Licensing, Registering & Advertising) Rules, 1976, hence Board decided to disposed off above applications.

Case no. 08 Priority as per Authority Decision of 129th meeting for Invalid Registration.

- Priority on the basis of decision of 129th meeting of the Authority wherein the Authority decided that "The Authority acceded to the request of firms for out-of-queue submission and consideration of registration dossiers on CTD Format (5F) in regard to cancelled products due to late submission of renewals."

503.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sarco Chemical Industries. 17-Km Peeray Wala Morr Khanewal Road Multan Pakistan**
	Name, address of Manufacturing site.	M/s Sarco Chemical Industries. 17-Km Peeray Wala Morr Khanewal Road Multan Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: RQW-JN2-SUXG dated 19-03-2024
	Details of fee submitted	Rs.30,000/- dated 14-03-2024
	The proposed proprietary name / brand name	**Sarodine Solution 10%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 50ml contains:** **Povidone iodine USP ..... 10% w/v** **Equivalent to 1% w/v of available Iodine**
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application..**		

Case no. 09 Miscellaneous cases

Following case was presented and approved on 331st meeting of Registration board while the minutes of the case could not be drafted inadvertently.

504.	Name, address of Applicant / Marketing Authorization Holder	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23135 dated 16-08-2022
	Details of fee submitted	Rs.75,000/- dated 07-07-2022
	The proposed proprietary name / brand name	**Synibac 4.5gm Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and Tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: Registration Board noted the correction in minutes and approved the instant application of Synibac 4.5gm Injection. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Following case was presented and approved on 335th meeting of Registration Board while the one of the strength i.e, **Flutrolz 250mcg/50mcg DPI Capsule** could not be mentioned in the decision, inadvertently.

505.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# J6N-SR4-HVQJ, 29-01-2024 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 250mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 250mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 231mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 500/50 mcg (fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 500mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114402)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and

		process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of both drug substances.
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 250mcg/50mcg (Powder for Inhalation) of GSK
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA			
API Lot No.		**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)		30’s Capsules packed in unit carton along with leaflet.	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		FSM-001	FSM-002
Batch Size		5000 Capsules	5000 Capsules
Manufacturing Date		01– 2023	01– 2023
No. of Batches		02	
506.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**	
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# BD6-515-DBUL, 29-01-2024 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 500mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 500mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 460mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 500/50 mcg (fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 500mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114402)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		both drug substances and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of both drug substances.
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 500mcg/50mcg (Powder for Inhalation) of GSK
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA		
API Lot No.	**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)	30’s Capsules packed in unit carton along with leaflet.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	FSH-001	FSH-002
Batch Size	5000 Capsules	5000 Capsules
Manufacturing Date	01– 2023	01– 2023
No. of Batches	02	

507.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# 25763, 25-10-2023 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 100mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 100mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 92mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 100/50 mcg (fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 100mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114400)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization,

		Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of both drug substances.
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30°C ± 2°C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 100mcg/50mcg (Powder for Inhalation) of GSK
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA		
API Lot No.	**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)	30's Capsules packed in unit carton along with leaflet.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	FSL-001	FSL-002
Batch Size	5000 Capsules	5000 Capsules
Manufacturing Date	01– 2023	01– 2023
No. of Batches	02	
Administrative Portion		

<table>
<tr><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>Firm has referred to onsite inspection report of this product:

XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)

which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021.
Registration Board decided to approve registration of
XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)
by M/s. Horizon Healthcare (Pvt) Ltd. Plot No. 35-A,
Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of XETINE 10mg Tablet, is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>GMP certificate of M/s VAMSI LABS LTD. is submitted, issued by FDA valid upto: 04-10-2024</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Clearance Certificate approved by DRAP attested by AD I&E, has been submitted.

Fluticasone Propionate:
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>SX-0070721</td><td>EXP/210/21-22</td><td>25.00 grams</td><td>29-Aug-2022</td></tr></table>
Salmeterol Xinafoate:
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>FTP-0120821</td><td>EXP/210/21-22</td><td>25.00 grams</td><td>29-Aug-2022</td></tr></table></td></tr>
<tr><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets have been submitted.</td></tr>
<tr><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing have been submitted.</td></tr>
<tr><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td colspan="2">Remarks of Evaluator II:

<table><tr><th>Section #</th><th>Observations</th><th>Firm’s response</th></tr></table></td></tr>
</table>

3.2.P.5.2	• Evidence of availability of emission spectrophotometer shall be submitted, required for the analysis of Fluticasone in drug product as per USP monograph.	Submitted

- Upon observation regarding product development prior to the section approval firm has referred to the panel inspection report dated 10-08-2022 & 16-08-2022, wherein availability of Copley Dry Powder Inhaler (required for testing of DPI products) & R&D lab has been declared.
- Following details of Drug delivery device to be accompanied with applied product has been submitted:

Name: Rotazone Inhaler Device
Manufactured by Shanghai Harui Aerosol Co.LtD No 222,yuanchun road Pudong new district shanghai,201399,P.R.China

Decision of 335th meeting: Registration Board approved the applications of Flutrolz 500mcg/50mcg DPI Capsule & Flutrolz 100mcg/50mcg DPI Capsule.

- Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
- Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Decision of 336th meeting: Registration Board noted the correction in minutes and approved the instant application of Flutrolz 250mcg/50mcg DPI Capsule

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of cases of New Section / New License

M/s Naeem Pharmaceuticals, Rahim Yar Khan. (New License)
Firm has been granted new license dated 26-10-2023 for following sections:

- Tablet (General) section
- Liquid injection vial (General) section
- Liquid injection ampoule (general) section
- Capsule (Cephalosporin) section
- Dry powder for injection (cephalosporin) section
- Dry powder for suspension (cephalosporin) section
- Cream / ointment (General) section
- Eye drops (General) section.

The details of applications of the firm is as under:

	Considered in M-335		**Currently applied**	
Section	**No of Molecules**	**No of products**	**No of Molecules**	**No of products**

Tablet (General) section	4	6	3	3
Liquid injection vial (General) section	1	1	4	4
Liquid injection ampoule (general) section	3	3	3	3
Capsule (Cephalosporin) section	1	2	2	4
Dry powder for injection (cephalosporin) section			3	12
Dry powder for suspension (cephalosporin) section	1	2	2	5
Cream / ointment (General) section				
Eye drops (General) section.			3	3

Firm has applied for following applications

Dry powder for suspension (cephalosporin) section

508.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. D86-JES-UARG: 15-05-2024
	Details of fee submitted	PKR 30,000/- : 29-04-2024
	The proposed proprietary name / brand name	**MONAXIME 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Suspension Contains: Cefixime as trihydrate……..100mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit report of verification studies of analytical method of drug substance.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

509.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. 3Q4-BE4-HTHS: 14-05-2024
	Details of fee submitted	PKR 30,000/- : 29-04-2024
	The proposed proprietary name / brand name	**MONAXIME 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Suspension Contains: Cefixime as trihydrate……..200mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit report of verification studies of analytical method of drug substance.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

510.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. N6T-8G1-94SD: 27-05-2024
	Details of fee submitted	PKR 30,000/- : 20-05-2024
	The proposed proprietary name / brand name	**FARCLOR 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cefaclor as monohydrate……..125mg

	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Ceclor suspension by AGP
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit report of verification studies of analytical method of drug substance.	Submitted
3.	Specify whether micrnozied or compacted API is used, since the submitted COA is for cefaclor compacted. Submit COA of relevant API used in the product.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

511.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. PRG-XT6-A78L: 27-05-2024
	Details of fee submitted	PKR 30,000/- : 20-05-2024
	The proposed proprietary name / brand name	**FARCLOR 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cefaclor as monohydrate……..250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Ceclor suspension by AGP
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API	Submitted

	manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit report of verification studies of analytical method of drug substance.	Submitted
3.	Specify whether micrnozied or compacted API is used, since the submitted COA is for cefaclor compacted. Submit COA of relevant API used in the product.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

512.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. Z74-3R2-G651: 27-05-2024
	Details of fee submitted	PKR 30,000/- : 20-05-2024
	The proposed proprietary name / brand name	**FARCLOR 50mg/ml Dry Suspension Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Reconstituted Suspension Contains: Cefaclor as monohydrate……..50mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved (as 250mg/5ml)
	For generic drugs (me-too status)	Ceclor drops by AGP
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Specify whether micrnozied or compacted API is used, since the submitted COA is for cefaclor compacted. Submit COA of relevant API used in the product.	Submitted.
4.	Clarify the difference between applied product (50mg/ml cefaclor powder for	Applied product (50mg/ml cefaclor powder for suspension) and 250mg/5ml cefaclor powder for suspension both are powder for

	suspension) and 250mg/5ml cefaclor powder for suspension	suspension but number of dose and volume after constitution is different in both cases during final packing dropper is added with drops and spoon for suspension for the proper use and dose as per prescribed by doctor.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Capsule (cephalosporin) section		
513.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. R27-TSS-DSEE: 15-05-2024
	Details of fee submitted	PKR 30,000/- : 29-04-2024
	The proposed proprietary name / brand name	**MONAXIME 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……..200mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved with Manufacturer's specifications as per monograph approved by Registration Board vide No. F.14-1/2022-PEC.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of Registration letter.**

514.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. RYS-NNU-GZ5Q: 13-05-2024
	Details of fee submitted	PKR 30,000/- : 29-04-2024
	The proposed proprietary name / brand name	**MONAXIME 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……..400mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved with Manufacturer's specifications as per monograph approved by Registration Board vide No. F.14-1/2022-PEC.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of Registration letter.**

515.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. GRU-6GH-5RU1: 28-05-2024
	Details of fee submitted	PKR 30,000/- : 20-05-2024
	The proposed proprietary name / brand name	**FARCLOR 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefaclor as monohydrate……..250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Ceclor capsule by AGP
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

516.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. GSW-JZN-2A3L: 24-05-2024
	Details of fee submitted	PKR 30,000/- : 20-05-2024
	The proposed proprietary name / brand name	**FARCLOR 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefaclor as monohydrate……..500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Ceclor capsule by AGP
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Dry powder for injection (cephalosporin) section		
517.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. NVR-488-XJZZ: 24-05-2024
	Details of fee submitted	PKR 30,000/- : 09-05-2024
	The proposed proprietary name / brand name	**NAFEPIME Injection 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime as hydrochloride…….250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**Could not be confirmed**
	For generic drugs (me-too status)	Cefstar injection by Barret Hodgson
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registraton Board in its 275th meeting.	RRA reference is not submitted.

2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
3.	Submit report of verification studies of analytical method of drug substance.	Submitted.
4.	Submit stability study data of API as per zone IV-A conditions.	Submitted.

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

i. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
ii. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
iii. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
iv. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

518.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. QS8-UJX-MDUU: 16-05-2024
	Details of fee submitted	PKR 30,000/- : 09-05-2024
	The proposed proprietary name / brand name	**NAFEPIME Injection 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime as hydrochloride…….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefstar injection by Barret Hodgson
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

3.	Submit stability study data of API as per zone IV-A conditions.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

519.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 9E7-5QM-EU9B: 13-05-2024
	Details of fee submitted	PKR 30,000/- : 09-05-2024
	The proposed proprietary name / brand name	**NAFEPIME Injection 1g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime as hydrochloride…….1g
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefstar injection by Barret Hodgson
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit stability study data of API as per zone IV-A conditions.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

520.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**

	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: VMN-MG7-GB7E: 22-05-2024
	Details of fee submitted	PKR 30,000/- : 09-05-2024
	The proposed proprietary name / brand name	**NAFEPIME Injection 2g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime as hydrochloride…….2g
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cefstar injection by Barret Hodgson
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit stability study data of API as per zone IV-A conditions.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

521.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: XEM-NM6-MBJY: 30-04-2024
	Details of fee submitted	PKR 30,000/- : 22-04-2024

	The proposed proprietary name / brand name	**MERAL 1G IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….1g
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Not submitted
2.	Submit report of verification studies of analytical method of drug substance.	Not submitted.

Decision: Deferred for the submission;

1. **specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.**
2. **Submit report of verification studies of analytical method of drug substance.**

522.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: WPQ-S63-BBTB: 10-05-2024
	Details of fee submitted	PKR 30,000/- : 26-04-2024
	The proposed proprietary name / brand name	**MERAL 2G IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….2g
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API	Submitted.

	manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit COA of relevant batch of API from both API manufacturer as well as product manufacturer	Submitted.
4.	Submit evidence of purchase of API	Submitted.
5.	Justify manufacturing of 2g ceftriaxone injection using API from Pharmagen Ltd while 1g ceftriaxone injection was manufactured using API from Zhuhai United Laboratories China.	Because material was received later.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

523.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 6T7-58R-WZY2: 08-05-2024
	Details of fee submitted	PKR 30,000/- : 22-04-2024
	The proposed proprietary name / brand name	**MERAL 250mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

3.	Submit COA of relevant batch of API from both API manufacturer as well as product manufacturer	Submitted.
4.	Submit evidence of purchase of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

524.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: E3G-9Q2-XWSE: 13-05-2024
	Details of fee submitted	PKR 30,000/- : 22-04-2024
	The proposed proprietary name / brand name	**MERAL 250mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit report of verification studies of analytical method of drug substance.	Submitted
3.	Submit COA of relevant batch of API from both API manufacturer as well as product manufacturer	Submitted
4.	Submit evidence of purchase of API	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

525.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: SY2-HHV-WM5L: 08-05-2024
	Details of fee submitted	PKR 30,000/- : 22-04-2024
	The proposed proprietary name / brand name	**MERAL 500mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit COA of relevant batch of API from both API manufacturer as well as product manufacturer	Submitted.
4.	Submit evidence of purchase of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

526.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: XL6-32Y-6NUN: 28-05-2024
	Details of fee submitted	PKR 30,000/- : 22-04-2024
	The proposed proprietary name / brand name	**MERAL 500mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone as sodium…….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Oxidil injection by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit COA of relevant batch of API from both API manufacturer as well as product manufacturer	Submitted.
4.	Submit evidence of purchase of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

527.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: BR4-JN1-BU7M: 09-05-2024
	Details of fee submitted	PKR 30,000/- : 04-05-2024
	The proposed proprietary name / brand name	**COMBOCEF 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone as sodium…….500mg Sulbactam as sodium…….500mg

	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g (**PMDA** Japan Approved)
	For generic drugs (me-too status)	Xorbact injection by Highnoon
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit stability data sheets for all stability batches	Submitted.
4.	Submit ADC attested invoice / clearance certificate for import of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

528.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: ETA-1HQ-7B1J: 21-05-2024
	Details of fee submitted	PKR 30,000/- : 04-05-2024
	The proposed proprietary name / brand name	**COMBOCEF 2g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone as sodium…….1g Sulbactam as sodium…….1g
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for injection

		Slovakia: Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	Xorbact injection by Highnoon
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit ADC attested invoice / clearance certificate for import of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Tablet General) section:		
529.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: L4Y-27T-EPNR: 13-05-2024
	Details of fee submitted	PKR 30,000/- : 23-04-2024
	The proposed proprietary name / brand name	**LEVOVA 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:- Levofloxacin Hemihydrate eq. to Levofloxacin ……..250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Leflox Tablet by Getz
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
530.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: L4Y-27T-EPNR: 09-05-2024
	Details of fee submitted	PKR 30,000/- : 23-04-2024
	The proposed proprietary name / brand name	**MOXINN 400mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:- Moxifloxacin as HCl……..400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Moxiget Tablet by Getz
	Proposed Pack size & Price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
531.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: TEZ-SPM-JGQ2: 08-05-2024
	Details of fee submitted	PKR 30,000/- : 02-05-2024
	The proposed proprietary name / brand name	**SIBGHALID 400mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid 400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Linzo Tablet by Maxitech
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit loan letter	Submitted.
2.	Submit analytical record of stability studies	Not Submitted
3.	As per the submitted clearance certificate, the API was imported by Semos pharma on 08-01-2024 while your stability data sheets show that the batches are manufactured in October 2023. Clarification is required in this regard.	Not submitted.

Proceeding of the 336th meeting: The board was appraised that the reply has been received, evaluated and found that the firm has submitted the reuired documents.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Liquid injection ampoule (general) section		
532.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: ZJE-TD4-UBWG: 27-05-2024
	Details of fee submitted	PKR 30,000/- : 14-05-2024
	The proposed proprietary name / brand name	**NYCACIN 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule contains: Amikacin as Sulphate……..500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved

	For generic drugs (me-too status)	Amkay Injection by Bosch
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit report of verification studies of analytical method of drug substance.	
3.	Submit COA of relevant batch of API from both API manufacture as well as drug product manufacturer.	
4.	Specify the fill volume whether 1ml or 2ml.	
5.	Submit GMP certificate of API manufacturer	
6.	Submit evidence of procurement of API	

Decision: Deferred for following:

- **Specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.**
- **Report of verification studies of analytical method of drug substance.**
- **COA of relevant batch of API from both API manufacture as well as drug product manufacturer.**
- **Specify the fill volume whether 1ml or 2ml.**
- **GMP certificate of API manufacturer.**
- **Evidence of procurement of API**

533.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: TB3-9PG-2GB5: 10-05-2024
	Details of fee submitted	PKR 30,000/- : 02-05-2024
	The proposed proprietary name / brand name	**NELOFER 5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml ampoule contains: - Iron As Sucrose……..100mg
	Pharmacotherapeutic Group of (API)	Hematinic
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**TGA** Approved
	For generic drugs (me-too status)	Venofer Injection by Searle
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit report of verification studies of analytical method of drug substance.	
3.	Submit COA of relevant batch of API from both API manufacture as well as drug product manufacturer.	
4.	Submit GMP certificate of API manufacturer	
5.	Submit evidence of procurement of API	
6.	Submit analytical record of stability studies.	

Decision: Deferred for following:

- **Specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.**
- **Report of verification studies of analytical method of drug substance.**
- **COA of relevant batch of API from both API manufacture as well as drug product manufacturer.**
- **GMP certificate of API manufacturer.**
- **Evidence of procurement of API.**
- **Analytical record of stability studies.**

534.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: M6Y-29M-415R: 30-05-2024
	Details of fee submitted	PKR 30,000/- : 24-05-2024
	The proposed proprietary name / brand name	**NIACAIN 1% Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Lidocaine HCl.....10mg
	Pharmacotherapeutic Group of (API)	Anesthetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Epocain 1% Injection by Epoch Pharma
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product	Submitted.

	manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit COA of relevant batch of API from both API manufactuer as well as drug product manufacturer.	Submitted.
4.	Specify the fill volume whether 1ml or 2ml.	Submitted.
5.	Submit GMP certificate of API manufacturer	Submitted.
6.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Liquid injection vial (General) section		
535.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: PP4-6BU-AJVD: 29-05-2024
	Details of fee submitted	PKR 30,000/- : 24-05-2024
	The proposed proprietary name / brand name	**CIPROVA DS 400mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml infusion contains: Ciprofloxacin as HCl……..400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Novidat infusion by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

3.	Justify why the master formulation is qualitatively different from innovator's product.	we have used ingredients which are recommended from handbook of pharmaceutical excipients. Furthermore we will perform stability realtime and accelerated to verify our formulation.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

536.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 3U3-EET-UNTV: 16-05-2024
	Details of fee submitted	PKR 30,000/- : 04-05-2024
	The proposed proprietary name / brand name	**DIAROL 500mg Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml infusion contains: Metronidazole……..500mg
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Flagyl infusion by Sanofi aventis
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit evidence of purchase of API	Submitted.
4.	Submit analytical record of stability testing.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

537.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: BUX-RR3-ZJ4S: 13-05-2024
	Details of fee submitted	PKR 30,000/- : 29-04-2024
	The proposed proprietary name / brand name	**MOXINN 400mg/250ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml vial contains: Moxifloxacin as HCl……..400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Mofest 400ml/250ml Infusion by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Specify whether your section is for small volume parenteral or large volume	Our section is small volume parenterals and it is valid upto 100ml.

Decision: Deferred for clarification whether the manufacturing facility is for small volume parenteral or large volume parenteral.

538.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: SRB-L6V-84HA: 20-05-2024
	Details of fee submitted	PKR 30,000/- : 02-05-2024
	The proposed proprietary name / brand name	**SIBGHALID 600mg/300ml Infusion**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 300ml vial contains: Linezolid 600mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Ecasil Infusion by Sami
	Proposed Pack size & Price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit loan letter	Submitted.
2.	Submit analytical record of stability studies	Not submitted.
3.	As per the submitted clearance certificate, the API was imported by Semos pharma on 08-01-2024 while your stability data sheets show that the batches are manufactured in October 2023. Clarification is required in this regard.	Not submitted.
4.	Specify whether your section is for small volume parenterals or large volume	This is to inform that the Section is Large Volume Parenteral (100ml and above)

Decision: Deferred for following:

- **Clarification whether the manufacturing facility is for small volume parenteral or large volume parenteral.**
- **Analytical record of stability studies.**
- **Clarification that the API was imported by Semos pharma on 08-01-2024 while your stability data sheets show that the batches are manufactured in October 2023.**

Eye drops (General) section		
539.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 4B4-RB1-31W4: 27-05-2024
	Details of fee submitted	PKR 30,000/- : 25-05-2024
	The proposed proprietary name / brand name	**ASIMO PRED 1% Opthalmic suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Prednisolone Acetate eq to Prednisolone ……. 10 mg
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved

	For generic drugs (me-too status)	Pred Forte Eye drops by Allergan
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.
3.	Submit API stability study data as per zone IV-A conditions	Submitted.
4.	Submit GMP certificate of API manufacturer	Submitted.
5.	Submit evidence of procurement of API	Submitted.
6.	Submit stability data sheets of all batches	Submitted.
7.	Submit complete analytical record of stability studies	Submitted.
8.	Justify why water loss studies is not performed while the container slosure system is LDPE Bottle.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

540.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: GHA-5HE-X94W: 29-05-2024
	Details of fee submitted	PKR 30,000/- : 27-05-2024
	The proposed proprietary name / brand name	**OPTADROZ 2% Ophthalmic solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dorzolamide HCl eq. to Dorzolamide ……. 20mg
	Pharmacotherapeutic Group of (API)	Antiglaucoma preparations
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Trusopt Eye drops by Searle
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of API manufacturer	Submitted.
2.	Submit evidence of procurement of API	Submitted.
3.	Submit complete analytical record of stability studies	Submitted.
4.	Specify wthere the container closure system is LDPE or HDPE.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

541.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: TZH-91E-82V6: 30-05-2024
	Details of fee submitted	PKR 30,000/- : 27-05-2024
	The proposed proprietary name / brand name	**GLAUOL 0.5% Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Timolol Maleate eq. to Timolol……..5mg
	Pharmacotherapeutic Group of (API)	Antiglaucoma preparations
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Nyolol Eye drops by Novartis
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of API manufacturer	Submitted.
2.	Submit evidence of procurement of API	Submitted.
3.	Submit complete analytical record of stability studies	Submitted.
4.	Specify wthere the container closure system is LDPE or HDPE.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal. (New Section)
Firm has been granted new license dated 03-03-2023 for following sections:

- Oral liquid (Human) new
- Capsule (Human) New

The details of applications of the firm is as under:

	Currently applied	
Section	**No of Molecules**	**No of products**
Capsule (Human) New	7	8

Firm has applied for following applications

542.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: EYW-UTY-8TYA: 28-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**EXON 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Esomeprazole magnesium trihydrate enteric coated pellets eq to esomeprazole…..20mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Nexum capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

543.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**

	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: GZG-Q6Y-RWLD: 23-04-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**EXON 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Esomeprazole magnesium trihydrate enteric coated pellets eq to esomeprazole…..40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Nexum capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

544.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: HEX-JXE-YHDA: 17-04-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**KOMIZOLE 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Omeprazole(as enteric coated pellets)…..40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Risek capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

545.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 6XJ-YHV-J64P: 26-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**ITCAN 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Itraconazole (as IR Pellets)……100 mg
	Pharmacotherapeutic Group of (API)	Antimycotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Fewnol 100mg capsule by Dew Max
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

546.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: MT7-J5Q-L94Q: 23-04-2024

	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**TAMSE 0.4mgCapsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tamsulosin HCl (as Sustained Release Pellets)……..0.4 mg
	Pharmacotherapeutic Group of (API)	Adrenergic alpha-1 Receptor Antagonists
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Maxflow 0.4mg Capsule By CCL Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

547.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: RVE-NV6-YBZH: 19-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**LOXET 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Duloxetine hydrochloride enteric coated pellets eq to duloxetine ……60mg
	Pharmacotherapeutic Group of (API)	Anti-depressant
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Hapibar 60 mg capsule By Barret Hodgson
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

548.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: XV1-4PW-9L6R: 28-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**DICLONOOR SR 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Diclofenac sodium (as SR Pellets) = 100 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Phlogin SR 100 mg capsule By Brookes
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

549.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.**
	Name, address of Manufacturing site.	M/s Kohinoor Industries 159-160/B, Small Industries Estate, Sahiwal.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: SSL-2EG-4MXA: 25-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**PREGNOOR 75mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin …… 75 mg
	Pharmacotherapeutic Group of (API)	Dual serotonin and norepinephrine reuptake inhibitor
	Reference to Finished product specifications	BP

	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Gabica capsule By Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of procurement of API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat. (New License)

Firm has submitte copy of letter of grant of new DML dated 14-02-2020 specifying Soft gel capsule (General) section.
Firm has submitted following applications.

550.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: HTB-DQS-WVTH: 01-03-2024
	Details of fee submitted	PKR 30,000/- : 19-02-2024
	The proposed proprietary name / brand name	**CALCIGEN 0.25mcg Soft gel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains:- calcitriol……..0.25mcg
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Calcitriol 0.25mcg Soft gel capsule by RG Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.

2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

551.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: EHL-H7T-1TW2: 19-04-2024
	Details of fee submitted	PKR 30,000/- : 15-01-2024
	The proposed proprietary name / brand name	**CALCIGEN 0.5mcg Soft gel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains:- calcitriol……..0.5mcg
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	G-Trol 0.5mcg Soft gel capsule by Global
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Submit report of verification studies of analytical method of drug substance.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Seraph Pharmaceuitcal, Islamabad (New Section)

M/s Seraph Pharmaceuitcal, Islamabad has been granted new section by CLB vide letter dated 06-03-2024 for following sections:

a) Liquid Syrup (General) section in place of Tablet I (General) section.

Moreover, the letter also specifies that the Registration Board may take the decision of the registration of drugs granted for Tablet-I (General) section.
Firm has applied for following applications

552.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. J81-GM5-SBZS: 23-04-2024
	Details of fee submitted	PKR 75,000/- : 21-03-2024
	The proposed proprietary name / brand name	**LIOREX 5mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Baclofen ……5mg
	Pharmacotherapeutic Group of (API)	AntiSpasmodic agent
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

553.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. QX7-NW6-23RB: 07-05-2024
	Details of fee submitted	PKR 30,000/- : 05-04-2024
	The proposed proprietary name / brand name	**MEMXIO 10mg/5ml oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Memantine hydrochloride Eq. to Memantine ……10mg
	Pharmacotherapeutic Group of (API)	Other Anti-dementia drugs
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Afdol 10mg/5ml oral solution by AGP
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we

		started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

554.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. TQ5-TAB-SS4Y: 18-04-2024
	Details of fee submitted	PKR 30,000/- : 21-03-2024
	The proposed proprietary name / brand name	**DESENT 2.5mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Desloratadine……2.5mg
	Pharmacotherapeutic Group of (API)	Antihistamines
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Neo-Antial Syrup by Sami Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup

		dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

555.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. GAE-J8Q-QPBJ: 18-04-2024
	Details of fee submitted	PKR 30,000/- : 21-03-2024
	The proposed proprietary name / brand name	**ORIS 1mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Risperidone ……1mg
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	PERSCH Oral Solution by Barrett Hodgson
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity

		assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

556.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. 8HD-TYL-7Y68: 18-04-2024
	Details of fee submitted	PKR 30,000/- : 21-03-2024
	The proposed proprietary name / brand name	**RESTON 4mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron hydrochloride dihydrate eq. to ondansetron……4mg
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Onsetron 4mg/5ml oral solution by Dyson
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to

		the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

557.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. 38W-BH9-L2S9: 18-04-2024
	Details of fee submitted	PKR 30,000/- : 21-03-2024
	The proposed proprietary name / brand name	**EBESTOL 5mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ebastine……5mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**Spain** Approved
	For generic drugs (me-too status)	Kestine Syrup by Highnoon
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management

	manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

558.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. BBS-GLM-8859: 27-05-2024
	Details of fee submitted	PKR 75,000/- : 16-05-2024
	The proposed proprietary name / brand name	**Preget 20mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of oral solution contains: Pregabalin……..20mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant drug
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm

1.	Central Licensing Board has granted Liquid syrup (General) section in place of Tablet-I (General) section. Clarify how the manufacturing of tablets will be carried out in your facility furthermore also specify the status of products registered in this section.	Initially, we had two tablet sections, Tablet I and Tablet II, within our facility. Recognizing that Tablet I was underutilized, our management made the strategic decision to convert it into a liquid syrup section. Subsequently, we applied for and received approval for this conversion (please refer to the attached approval letter for verification). Additionally, Tablet II section is already operational, and a capacity assessment conducted by DRAP confirms that it meets our production requirements (Capacity assessment report dated 08-03-2024 was conducted after syrup section approval).
2.	Justify the manufacturing of stability batches before the approval of section from Central Licensing Board.	We already have well equipped Research and Development department established within our facility which are supporting to syrup dosage form development (the section approval letter is attached. And syrup section inspection report is also attached which was conducted on 07th December 2023 and we started the product development after this date.)
3.	Submit 6 months stability study data	Stability data will be completed in June 2024, we will submit 6th month data immediately after analysis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

559.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. GWA-WXL-P8JG: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 27-04-2023
	The proposed proprietary name / brand name	**CEFOSS 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Sodium eq. to Ceftizoxime ...500mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cefizox Injection by Barrett Hodgson
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefizox injection of Barret Hodgson.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China		
API Lot No.	12C0302104005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-69	TR-CEP-70	TR-CEP-71
Batch Size	1719 vials	1719 vials	1719 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	17-09-2021	17-09-2021	17-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of AD attested commercial invoice dated 13-08-2021 specifying 10kg ceftizoxime.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	The product is discontinued in FDA without specifying the reason.
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.

3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Analyical method verification studies performed on drug product shall be same as performed for drug substance since no excipient is used.
4.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	Submitted.
6.	Specify the fill weight of the product per vial.	Submitted.
7.	Submit preservative effectiveness studies	Submitted
8.	Submit microbial attributes of the drug product	Submitted
9.	Submit compatibility studies in section 3.2.P.2.6	Submitted
10.	Submit GMP certificate of API manufacturer since the submitted GMP certificate specifies different name and address.	Copy of Manufacturing License of API manufacturer issued by NMPA China valid till 26-10-2025.
11.	Submit BMR of three stability batches.	Submitted

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

i. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
ii. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
iii. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
iv. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

Case No. 02 Registration applications of Export Facilitation

560.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 26-06-2022 is submitted.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued dated 04-04-2022 on the basis of inspection dated 07-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section which specifies Injectable ampoules BF (Steroid).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9423: 07-04-2023
	Details of fee submitted	PKR 75,000/-: 21-03-2023
	The proposed proprietary name / brand name	**BECSON 0.8mg/2ml Nebulization Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of Suspension Contains: Beclomethasone Dipropionate…0.8mg
	Pharmaceutical form of applied drug	LDPE ampoules
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	AIFA Italy Approved (Firm has submitted the link of AIFA database, however the database is not accessable)
	For generic drugs (me-too status)	Clenil by Chiesi Pharmaceutical
	Name and address of API manufacturer.	FARMABIOS S.P.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Clenil Suspension
	Analytical method validation/verification of	Firm has submitted verification studies of the drug

	product	substance and the drug product.		
STABILITY STUDY DATA				
Manufacturer of API	FARMABIOS S.P.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.			
API Lot No.	2106DM4			
Description of Pack (Container closure system)	LDPE ampoule			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	SB-BD-NU-04	SB-BD-NU-05	SB-BD-NU-06	
Batch Size	2 L	2 L	2 L	
Manufacturing Date	12-2021	12-2021	12-2021	
Date of Initiation	03-01-2022	03-01-2022	03-01-2022	
No. of Batches	03			
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to its previous inspection conducted for Bufen Injection 100mg. The inspection was conducted on 11-05-2018 and was considered by the Board in its 282nd meeting of RB.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Eudra GMP certificate issued on the basis of inspection dated 12-06-2020.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 20g Beclomethasone. The invoice is clearance by AD (I&E) DRAP dated 10-12-2021.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report of stability testing		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Evaluation by PEC:				
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**				
561.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**		
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority,		

		Karachi Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 26-06-2022 is submitted.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued dated 04-04-2022 on the basis of inspection dated 07-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section which specifies Injectable ampoules BF (Steroid).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9422: 07-04-2023
	Details of fee submitted	PKR 75,000/-: 21-03-2023
	The proposed proprietary name / brand name	**Becson Plus 0.8mg+1.6mg/2ml Nebulization Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of Suspension Contains: Beclomethasone Dipropionate…0.8mg Salbutamol Sulphate…1.6mg
	Pharmaceutical form of applied drug	LDPE ampoules
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	AIFA Italy Approved (Firm has submitted the link of AIFA database, however the database is not accessable)
	For generic drugs (me-too status)	Clenil by Chiesi Pharmaceutical
	Name and address of API manufacturer.	FARMABIOS S.P.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Clenil Suspension
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	FARMABIOS S.P.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.		
API Lot No.	2106DM4		
Description of Pack (Container closure system)	LDPE ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SB-BD-NU-04	SB-BD-NU-05	SB-BD-NU-06
Batch Size	2 L	2 L	2 L
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	03-01-2022	03-01-2022	03-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to its previous inspection conducted for Bufen Injection 100mg. The inspection was conducted on 11-05-2018 and was considered by the Board in its 282nd meeting of RB.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Eudra GMP certificate issued on the basis of inspection dated 12-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 20g Beclomethasone. The invoice is clearance by AD (I&E) DRAP dated 10-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report of stability testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

562.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5100: 22-02-2023
	Details of fee submitted	PKR 30,000/-: 23-12-2022
	The proposed proprietary name / brand name	**EMPOZIN 3XR 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)…5mg Linagliptin (Immediate Release)…2.5mg Metformin Hcl (Extended Release)…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China

		Metformin hydrochloride: Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China	

	Metformin hydrochloride: Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China		
API Lot No.	**Empagliflozin:** H-E-20211005-D04-E06-01 **Metformin hydrochloride:** MET/061/21 **Linagliptin:** L-20190305-D01-L09-08		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-031-001	22SB-032-002	22SB-033-003
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	21-06-2022	21-06-2022	21-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 287th meeting dated 03rd & 04th January, 2019 decided to approve registration of Mac-Fenid Tablet 267mg & Mac-Fenid Tablet 801mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027. **Metformin HCl:** Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 28-08-2025. **Linagliptin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-01-2022 for import of 30kg of Empagliflozin. The invoice is attested by AD (I&E) DRAP. **Metformin HCl:** Firm has submitted copy of commercial invoice cleared dated 07-02-2022 for import of 500kg of Metformin HCl. The invoice is attested by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial invoice cleared dated 04-03-2020 for import of 1.5kg of Linagliptin. The invoice is attested by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The me-too status of the product is not available while the firm has only submitted 30,000 fee for registration.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 45,000/- balance fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

563.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4929: 21-02-2023
	Details of fee submitted	PKR 30,000/-: 22-12-2022
	The proposed proprietary name / brand name	**EMPOZIN 3XR 12.5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)…12.5mg Linagliptin (Immediate Release)…2.5mg Metformin Hcl (Extended Release)…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China		
API Lot No.	**Empagliflozin:** H-E-20211005-D04-E06-01 **Metformin hydrochloride:** MET/061/21 **Linagliptin:** L-20190305-D01-L09-08		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-037-001	22SB-038-002	22SB-039-003
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	24-06-2022	24-06-2022	24-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 287th meeting dated 03rd & 04th January, 2019 decided to approve registration of Mac-Fenid Tablet 267mg & Mac-Fenid Tablet 801mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027. **Metformin HCl:** Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 28-08-2025. **Linagliptin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-01-2022 for import of 30kg of Empagliflozin. The invoice is attested by AD (I&E) DRAP. **Metformin HCl:** Firm has submitted copy of commercial invoice cleared dated 07-02-2022 for import of 500kg of Metformin HCl. The invoice is attested by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial invoice cleared dated 04-03-2020 for import of 1.5kg of Linagliptin. The invoice is attested by AD (I&E) DRAP.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The me-too status of the product is not available while the firm has only submitted 30,000 fee for registration.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 45,000/- balance fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

564.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 365: 04-01-2023
	Details of fee submitted	PKR 30,000/-: 22-12-2022
	The proposed proprietary name / brand name	**EMPOZIN 3XR 10/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)…10mg Linagliptin (Immediate Release)…5mg Metformin Hcl (Extended Release)…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance.

		Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China		
API Lot No.	**Empagliflozin:** H-E-20211005-D04-E06-01 **Metformin hydrochloride:** MET/061/21 **Linagliptin:** L-20190305-D01-L09-08		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-034-001	22SB-035-002	22SB-036-003
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	22-06-2022	22-06-2022	22-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 287th meeting dated 03rd & 04th January, 2019 decided to approve registration of Mac-Fenid Tablet 267mg & Mac-Fenid Tablet 801mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027. **Metformin HCl:** Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 28-08-2025. **Linagliptin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-01-2022 for import of 30kg of Empagliflozin. The invoice is attested by AD (I&E) DRAP. **Metformin HCl:** Firm has submitted copy of commercial invoice cleared dated 07-02-2022 for import of 500kg of Metformin HCl. The invoice is attested by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial

		invoice cleared dated 04-03-2020 for import of 1.5kg of Linagliptin. The invoice is attested by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The me-too status of the product is not available while the firm has only submitted 30,000 fee for registration.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 45,000/- balance fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

565.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2548: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 22-12-2022
	The proposed proprietary name / brand name	**EMPOZIN 3XR 25/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)…25mg Linagliptin (Immediate Release)…5mg Metformin HCl (Extended Release)…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.

	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China **Metformin hydrochloride:** Abhilasha Pharma Pvt. Ltd. No. 1408,1409, G.I.D.C. Estate, Ankleshwar- 393 002, Gujarat India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County Fuxin City, Liaoning Province, China		
API Lot No.	**Empagliflozin:** H-E-20211005-D04-E06-01 **Metformin hydrochloride:** MET/061/21 **Linagliptin:** L-20190305-D01-L09-08		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-040-001	22SB-041-002	22SB-042-003
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-06-2022	27-06-2022	27-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 287th meeting dated 03rd & 04th January, 2019 decided to approve registration of Mac-Fenid Tablet 267mg & Mac-Fenid Tablet 801mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027. **Metformin HCl:** Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 28-08-2025. **Linagliptin:** Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-01-2022 for import of 30kg of Empagliflozin. The invoice is attested by AD (I&E) DRAP. **Metformin HCl:** Firm has submitted copy of commercial invoice cleared dated 07-02-2022 for import of 500kg of Metformin

		HCl. The invoice is attested by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial invoice cleared dated 04-03-2020 for import of 1.5kg of Linagliptin. The invoice is attested by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
• The me-too status of the product is not available while the firm has only submitted 30,000 fee for registration.		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration Board further decided that registration letter will be issued after submission of 45,000/- balance fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

566.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 15-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-06-2021 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3129: 02-02-2023
	Details of fee submitted	PKR 75,000/-: 24-01-2023
	The proposed proprietary name / brand name	**EMLIMET XR 2.5/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Empagliflozin…5mg Metformin Hcl…1000mg

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
API Lot No.	**Empagliflozin:** EGLZ-RD202108002 **Metformin hydrochloride:** MEF/11072154 **Linagliptin:** LGLT-RD202101101		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-248-01	22SB-249-02	22SB-250-03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	08-07-2022	08-07-2022	08-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for

		alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Firm has submitted following revised label claim along with submission of 75,000 fee. Each Film Coated Extended Release Tablet Contains: Linagliptin (Immediate Release)…2.5mg Empagliflozin (Immediate Release)…5mg Metformin HCl (Extended Release)…1000mg
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted.
3.	Submit verification studies of analytical method of each drug substance performed by drug product manufacturer.	Submitted.
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted.
5.	Submit valid GMP certificate of each API manufacturer	Submitted.
6.	Submit documents confirming import of each API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

567.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 15-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-06-2021 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5804: 01-03-2023
	Details of fee submitted	PKR 75,000/-: 31-01-2023
	The proposed proprietary name / brand name	**EMLIMET XR 5/10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…10mg Metformin Hcl…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process

		and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
API Lot No.	**Empagliflozin:** EGLZ-RD202108002 **Metformin hydrochloride:** MEF/11072154 **Linagliptin:** LGLT-RD202101101		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-245-01	22SB-246-02	22SB-247-02
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet

Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	18-07-2022	18-07-2022	18-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Firm has submitted following revised label claim along with submission of 75,000 fee. Each Film Coated Extended Release Tablet Contains: Linagliptin (Immediate Release)….5mg Empagliflozin (Immediate Release)…10mg Metformin HCl (Extended Release)…1000mg
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the	Submitted.

	Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
3.	Submit verification studies of analytical method of each drug substance performed by drug product manufacturer.	Submitted.
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted.
5.	Submit valid GMP certificate of each API manufacturer	Submitted.
6.	Submit documents confirming import of each API	Submitted.
7.	Submit stability study data of 3 batches of drug product as per the 6 points checklist. Since data sheet of only 2 batches is submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

568.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 15-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-06-2021 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3128: 02-02-2023
	Details of fee submitted	PKR 75,000/-: 24-01-2023
	The proposed proprietary name / brand name	**EMLIMET XR 2.5/12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Empagliflozin…12.5mg Metformin Hcl…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against

		the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
API Lot No.	**Empagliflozin:** EGLZ-RD202108002 **Metformin hydrochloride:** MEF/11072154 **Linagliptin:** LGLT-RD202101101		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-217-01	22SB-218-02	22SB-219-03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	27-06-2022	27-06-2022	27-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Firm has submitted following revised label claim along with submission of 75,000 fee. Each Film Coated Extended Release Tablet Contains: Linagliptin (Immediate Release)….2.5mg Empagliflozin (Immediate Release)…12.5mg Metformin HCl (Extended Release)…1000mg
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted.
3.	Submit verification studies of analytical method of each drug substance performed by drug product manufacturer.	Submitted.
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted.
5.	Submit valid GMP certificate of each API manufacturer	Submitted.
6.	Submit documents confirming import of each API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

569.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 15-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-06-2021 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4040: 13-02-2023
	Details of fee submitted	PKR 75,000/-: 31-01-2023
	The proposed proprietary name / brand name	**EMLIMET XR 5/25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…25mg Metformin Hcl…1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Metformin hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as [er zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Trijardy XR Tablet. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Trijardy XR Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA. **Linagliptin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
API Lot No.	**Empagliflozin:** EGLZ-RD202108002 **Metformin hydrochloride:** MEF/11072154 **Linagliptin:** LGLT-RD202101101		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-182-01	22SB-183-02	22SB-184-03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022

Date of Initiation	14-06-2022	14-06-2022	14-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Firm has submitted following revised label claim along with submission of 75,000 fee. Each Film Coated Extended Release Tablet Contains: Linagliptin (Immediate Release)….5mg Empagliflozin (Immediate Release)…25mg Metformin HCl (Extended Release)…1000mg
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical	Submitted.

	Ingredient by both Drug substance & Drug Product manufacturer is required."	
3.	Submit verification studies of analytical method of each drug substance performed by drug product manufacturer.	Submitted.
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted.
5.	Submit valid GMP certificate of each API manufacturer	Submitted.
6.	Submit documents confirming import of each API	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 03 Priority as per Authority Decision of 129th meeting for Invalid Registration

Priority on the basis of decision of 129th meeting of the Authority wherein the Authority decided that "The Authority acceded to the request of firms for out-of-queue submission and consideration of registration dossiers on CTD Format (5F) in regard to cancelled products due to late submission of renewals."

M/s Hisun has submitted following applications for the products which were cancelled due to late submission of renewals. The details of cancellation letter of the firm is tabulated below:

Sr. No	Registration No	Brand Name	Date & File No of cancellation of Registration
1.	051063	Predcort syrup Each ml contains: Prednisolone……..15mg	F.No.3-5/2021-RRR (M-312) 08-12-2021
2.	056474	Pizosun Syrup Each 5ml contains: Pizotifen (as hydrogen maleate)……0.25mg	F.No.3-8/2022-RRR (M-317) 05-07-2022
3.	056480	Brosun Suspension Each 5ml contains: Ibuprofen…….100mg	F.No.3-8/2022-RRR (M-317) 05-07-2022
4.	056477	Cetsun Syrup Each 5ml contains: Cetirizine 2HCl……5mg	F.No.3-8/2022-RRR (M-317) 05-07-2022
5.	056486	Cetsun 10mg Tablet Each tablet contains: Cetirizine 2HCl……10mg	F.No.3-8/2022-RRR (M-317) 05-07-2022

570.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19987: 11-08-2023
	Details of fee submitted	PKR 30,000/-: 13-06-2023
	The proposed proprietary name / brand name	**PREDICOT 15mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Oral Solution Contains: Prednisolone……15mg
	Pharmaceutical form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml, 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Rapicort Syrup by Tabros pharma
	Name and address of API manufacturer.	Zhejiang Xianju Pharmaceutical Co Ltd. 1 Xianyao Road Xianju Zhejiang China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Rapicort Syrup of Tabros
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Xianju Pharmaceutical Co Ltd. 1 Xianyao Road Xianju Zhejiang China		
API Lot No.	X8-190710		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-020	T-021	T-022
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	15-09-2022	15-09-2022	15-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit letter of cancellation of registration of your already registered product, since you have applied for out of queue consideration of this product based on the reason that it has been cancelled due to non submission of renewal in time.	
2.	Submit evidence of requisite manufacturing facility i.e. Liquid syrup (steroid) section from Licensing Division DRAP.	
3.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
4.	Submit details including IR spectra for characterization of API in section 3.2.S.3.	
5.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
6.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
7.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
8.	Submit COA of reference standard used in the analysis of drug substance.	
9.	Submit stability study data of 3 batches of drug substance, since the submitted data sheets are not of the API manufacturer.	
10.	Submit drug-excipient compatibility studies since the excipient used in your formulation are qualitatively different from the innovator's product.	
11.	Submit preservative effectiveness studies	
12.	Justify why pH test is not included in the drug product specification	
13.	The specifications of the drug product are different from USP monograph, justification is required in this regard.	
14.	Submit analytical method of drug product testing in section 3.2.P.5.2.	
15.	Submit valid GMP certificate of each API manufacturer	
16.	Submit documents confirming import of each API	
17.	Submit stability study data in a propoer sequence along with separators to identify different batches and time points as required in the CTD guidance document.	
18.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	

19.	Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
20.	Submit BMR of three stability batches.	

Proceedings: Registration Board noted that The DRAP Authority in its180th meeting held on 07th March 2024 decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

Since, DRAP Authority has decided to exempt such applications from submission of Form5-F, therefore the Board decided to evaluate the instant case as per the requirements of Form 5.

Decision: Registration Board deliberated the matter and in light of the decision of 180th meeting of the authority decided to defer the case for evidence of requisite manufacturing facility from Licensing Division within 1 month.

571.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML which specifies Liquid / syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19988: 11-08-2023
	Details of fee submitted	PKR 30,000/-: 13-06-2023
	The proposed proprietary name / brand name	**PIZOSUN 0.25mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Oral Solution Contains: Pizotifen maleate……0.25mg
	Pharmaceutical form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Antamines
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	60ml, 90ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Mosegor Syrup by Novartis
	Name and address of API manufacturer.	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, taicang City, Jiangsu province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Mosegor Syrup.
	Analytical method validation/verification of product	

STABILITY STUDY DATA	
Manufacturer of API	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, Taicang City, Jiangsu province, China.
API Lot No.	~~0210523~~
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-018	T-019	T-020
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	17-09-2022	17-09-2022	17-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit letter of cancellation of registration of your already registered product, since you have applied for out of queue consideration of this product based on the reason that it has been cancelled due to non submission of renewal in time.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit details including IR spectra for characterization of API in section 3.2.S.3.	
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	

7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit drug-excipient compatibility studies since the excipient used in your formulation are qualitatively different from the innovator's product.	
9.	Submit preservative effectiveness studies	
10.	Justify why pH test is not included in the drug product specification	
11.	Submit analytical method of drug product testing in section 3.2.P.5.2.	
12.	Submit valid GMP certificate of each API manufacturer	
13.	Submit documents confirming import of each API	
14.	Submit stability study data in a propoer sequence along with separators to identify different batches and time points as required in the CTD guidance document.	
15.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	
16.	Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
17.	Submit BMR of three stability batches.	

Proceedings: Registration Board noted that The DRAP Authority in its180th meeting held on 07th March 2024 decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

Since, DRAP Authority has decided to exempt such applications from submission of Form5-F, therefore the Board decided to evaluate the instant case as per the requirements of Form 5.

Decision: Registration Board deliberated the matter and in light of the decision of 180th meeting of the authority decided to approve the product.

572.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML which specifies Liquid / syrup (General) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21766: 04-09-2023
	Details of fee submitted	PKR 30,000/-: 13-06-2023
	The proposed proprietary name / brand name	**BROSUN 100mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension Contains: Ibuprofen……100mg
	Pharmaceutical form of applied drug	Oral Suspension
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Proposed Pack size	60ml, 90ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Brufen Suspension by Abbott
	Name and address of API manufacturer.	Zenith Chemical Industries (Pvt) Ltd. Moaza Dhonday Jia Bagga Raiwind Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard

		or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Brufen Suspension
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Zenith Chemical Industries (Pvt) Ltd. Moaza Dhonday Jia Bagga Raiwind Road Lahore.		
API Lot No.	ZIBU22-010		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-026	T-027	T-028
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	23-10-2022	23-10-2022	23-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit letter of cancellation of registration of your already registered product, since you have applied for out of queue consideration of this product based on the reason that it has been	

	cancelled due to non submission of renewal in time.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit details including IR spectra for characterization of API in section 3.2.S.3.	
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit drug-excipient compatibility studies since the excipient used in your formulation are qualitatively different from the innovator's product.	
9.	Submit preservative effectiveness studies	
10.	Justify why pH test is not included in the drug product specification	
11.	Submit analytical method of drug product testing in section 3.2.P.5.2.	
12.	Submit valid GMP certificate of each API manufacturer	
13.	Submit documents confirming import of each API	
14.	Submit stability study data in a propoer sequence along with separators to identify different batches and time points as required in the CTD guidance document.	
15.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	
16.	Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
17.	Submit BMR of three stability batches.	

Proceedings: Registration Board noted that The DRAP Authority in its180th meeting held on 07th March 2024 decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

Since, DRAP Authority has decided to exempt such applications from submission of Form5-F, therefore the Board decided to evaluate the instant case as per the requirements of Form 5. **Decision: Registration Board deliberated the matter and in light of the decision of 180th meeting of the authority decided to approve the product.**		
573.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML which specifies Liquid / syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21767: 04-09-2023
	Details of fee submitted	PKR 30,000/-: 13-06-2023
	The proposed proprietary name / brand name	**CETSUN 5mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of oral solution Contains: Cetrizine dihydrochloride……5mg
	Pharmaceutical form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Anti Allergy
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml, 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Rigix Oral Solution by AGP
	Name and address of API manufacturer.	Mahrshee Laboratories Pvt Ltd. Unit-I Plot No, 3014-15 GIDC Estate Phase-III Panoli Ankleshwar India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	Mahrshee Laboratories Pvt Ltd. Unit-I Plot No, 3014-15 GIDC Estate Phase-III Panoli Ankleshwar India		
API Lot No.	CTZ/009/21-22		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-015	T-016	T-017
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	09-11-2022	09-11-2022	09-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit letter of cancellation of registration of your already registered product, since you have applied for out of queue consideration of this product based on the reason that it has been cancelled due to non submission of renewal in time.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit details including IR spectra for characterization of API in section 3.2.S.3.	
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit stability study data of 3 batches of drug substance, since the submitted data sheets are not of the API manufacturer.	
9.	Submit evidence of testing of sorbitol (used as excipient) to confirm testing of toxic impurities i.e. DEG and EG.	
10.	Submit drug-excipient compatibility studies since the excipient used in your formulation are qualitatively different from the innovator's product.	
11.	Submit pharmaceutical equivalence studies of the drug product.	
12.	Submit preservative effectiveness studies	
13.	The specifications of the drug product are different from USP monograph, justification is required in this regard.	

14.	Submit analytical method of drug product testing in section 3.2.P.5.2.	
15.	Submit validation studies of the analytical method of drug product.	
16.	Submit batch analysis report of three batches of drug product in section 3.2.P.5.4	
17.	Submit valid GMP certificate of each API manufacturer	
18.	Submit documents confirming import of each API	
19.	Submit stability study data in a propoer sequence along with separators to identify different batches and time points as required in the CTD guidance document.	
20.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	
21.	Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
22.	Submit BMR of three stability batches.	

Proceedings: Registration Board noted that The DRAP Authority in its180th meeting held on 07th March 2024 decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

Since, DRAP Authority has decided to exempt such applications from submission of Form5-F, therefore the Board decided to evaluate the instant case as per the requirements of Form 5.

Decision: Registration Board deliberated the matter and in light of the decision of 180th meeting of the authority decided to approve the product.

574.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries Plot No. 37-A, R-2, Industrial Estate Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18839: 26-07-2023

	Details of fee submitted	PKR 30,000/-: 13-06-2023
	The proposed proprietary name / brand name	**CETSUN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Cetrizine dihydrochloride……10mg
	Pharmaceutical form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Anti Allergy
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 15's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Rigix Tablet by AGP
	Name and address of API manufacturer.	Mahrshee Laboratories Pvt Ltd. Unit-I Plot No, 3014-15 GIDC Estate Phase-III Panoli Ankleshwar India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Rigix Tablet Firm has submitted result of CDP for their product against Rigix Tablet

	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Mahrshee Laboratories Pvt Ltd. Unit-I Plot No, 3014-15 GIDC Estate Phase-III Panoli Ankleshwar India		
API Lot No.	CTZ/009/21-22		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-015	T-016	T-017
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	09-11-2022	09-11-2022	09-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit letter of cancellation of registration of your already registered product, since you have applied for out of queue consideration of this product based on the reason that it has been cancelled due to non submission of renewal in time.	
2.	Revise your label claim as the reference product is film coated tabet while you have applied for uncoated tablet	
3.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	

4.	Submit details including IR spectra for characterization of API in section 3.2.S.3.	
5.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
6.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
7.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
8.	Submit COA of reference standard used in the analysis of drug substance.	
9.	Submit stability study data of 3 batches of drug substance, since the submitted data sheets are not of the API manufacturer.	
10.		
11.	Submit drug-excipient compatibility studies since the excipient used in your formulation are qualitatively different from the innovator's product.	
12.	Specify the exact dissolution test performed, since USP has specified 3 dissolution tests.	
13.	Submit analytical method of drug product testing in section 3.2.P.5.2.	
14.	Submit validation studies of the analytical method of drug product.	
15.	Submit batch analysis report of three batches of drug product in section 3.2.P.5.4	
16.	Submit valid GMP certificate of each API manufacturer	
17.	Submit documents confirming import of each API	
18.	Submit stability study data in a propoer sequence along with separators to identify different batches and time points as required in the CTD guidance document.	
19.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	
20.	Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
21.	Submit BMR of three stability batches.	
22.	Specify how many HPLc system are present in your QC lab since you have performed testing of cetirizine tablet and syrup on same day on similar time which is not possible on a single HPLC system.	

Proceedings: Registration Board noted that The DRAP Authority in its180th meeting held on 07th March 2024 decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

Since, DRAP Authority has decided to exempt such applications from submission of Form5-F, therefore the Board decided to evaluate the instant case as per the requirements of Form 5.

Decision: Registration Board deliberated the matter and in light of the decision of 180th meeting of the authority decided to approve the product.

Case No. 04 Registration applications of CTD cases

a. New cases

October 2022

575.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s City Pharmaceutical Laboratories Plot No. 12-A, I-5, Sector 5, New Survey No 276, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s City Pharmaceutical Laboratories Plot No. 12-A, I-5, Sector 5, New Survey No 276, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30040: 24-10-2022
	Details of fee submitted	PKR 30,000/- : 20-09-2022
	The proposed proprietary name / brand name	**PARACETAMOL 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol……500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic, antipyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved.
	For generic drugs (me-too status)	Panadol Tablet by GSK

	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Calpol Tablet of GSK. Firm has submitted result of CDP studies for their product against Calpol Tablet of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510911/078/2020		
Description of Pack (Container closure system)	Alu PVC Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	P5001	P5002	P5003

Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	25-10-2021	27-10-2021	29-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Name of the applicant / manufacturer mentioned in section 1.3.1 and 1.3.2 is "City Pharmaceuticals Laboratories" while the name of the firm mentioned on DML is "City Pharmaceutical Laboratories". Correction in the name is required along with submission of full fee of registration.	
2.	Submit valid GMP certificate / inspection report of drug product manufacturer.	
3.	Submit section approval letter from Licensing Division for the requisite manufacturing facility	
4.	Specify the exact brand name applied, since PARACETAMOL 500mg Tablet is mentioned in section 1.5.3 while Ferodol Tablet is mentioned on covering letter and rest of the application.	
5.	Submit GMP certificate of the drug substance manufacturer in section 1.6.5 (b).	
6.	Submit details in section 3.2.S.3 "Characterization" as per the CTD guidance document.	
7.	Submit discussion on the potential for isomerism and identification of stereochemistry, studies performed to identify potential polymorphic forms and particle size distribution of the Drug substance, since these parameters may impact the quality, safety or efficacy of the drug product in section 3.2.S.3.	
8.	Submit list of Drug Substance / API-related impurities and process-related impurities along with acceptance limits in section 3.2.S.3.	
9.	Submit specifications of drug substance from drug substance manufacturer in section 3.2.S.4.1, since you have submitted a document for analytical method in this section with header of	

	pharmagen limited however this method is not the actual method of the drug substance manufacturer.	
10.	Submit specifications of the drug substance from drug product manufacturer in section 3.2.S.4.1	
11.	Submit analytical procedure of the drug substance from drug substance manufacturer in section 3.2.S.4.2.	
12.	Submit analytical procedure of the drug substance from drug product manufacturer in section 3.2.S.4.2.	
13.	Submit verification studies of the analytical procedure for testing of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
14.	Justify the submission of COA of Batch No. 00510911/078/2020 in which the result of solubility is 619mg/Tab, result of water content is 5 min, result of sulphated ash (acceptance criteria NMT 0.1%) is 99.03% and result of melting point is 98.99%.	
15.	API manufacturer has specified the test of loss on drying in the drug substance specifications while you have mentioned water contents. Clarify how you can adopt different specifications from that specified by the drug substance manufacturer.	
16.	API manufacturer has specified the assay limit 99.0 – 101%, while you have mentioned the assay limit as 98 – 102%. Clarify how you can adopt different specifications from that specified by the drug substance manufacturer.	
17.	Submit evidence of procurement of USP reference standard used for analysis of drug substance as you have submitted the certificate of USP reference standard in section 3.2.S.5	
18.	The specifications of drug substance have been claimed as "BP" while the reference standard of "USP" has been used. Clarification is required in this regard.	
19.	The COA of working standard from pharmegn limited submitted in section 3.2.S.5 specifies use before 01 February 2018 while you have performed API testing in September 2021 justify how this COA can be used.	
20.	Submit stability study data of commercial batch of API performed by pharmagen since the submitted stability data is of a lab scale batch (25gm).	
21.	Submit clear readable copy of API stability study datam since the submitted data sheets are not readable.	
22.	Submit API stability study data for 3 batches.	
23.	Justify the CDP results at various time points where drug release at later time point is less than the drug release at earlier time point for a single unit. Justification is required in this regard.	
24.	Qualitative composition of your product is different from the innovator's product while compatibility studies are not performed. Clarification is required in this regard.	
25.	Justify the process validation protocols without identifying the critical quality attributes. Furthermore, the wet granulation and drying steps are not covered in this protocols. Moreover, clarify how the temperature and drying time will be selected and which type of dryer is used for the performance of the same.	
26.	BP has recommended that the concentration of sample solution in dissolution test shall be 0.00075% w/v of paracetamol, while your mehod specifies that the concentration of sample solution	

	is 0.011mg/ml. Justification is required how such change in dissolution method can be utilized.	
27.	Justify how you have claimed BP specifications while you have not included the test of related substances as specified in BP monograph.	
28.	Submit report of verification studies of the analytical procedure of the drug product in section 3.2.P.5.3.	
29.	Submit batch analysis certificate of three batches of drug product in section 3.2.P.5.4.	
30.	Submit evidence of procurement of USP reference standard Lot No K2M244 which is used for the analysis of drug product.	
31.	Section 3.2.P.7 specifies that the container closure system of the product is Alu-Alu blister while in stability data sheets the container closure system is mentioned as Alu PVC blister. Clarification is required in this regard.	
32.	You have mentioned that your firm is a new license in section 3.2.P.8.3. Justification is required in this regard.	
33.	Submit readable copy of GMP certificate of the API manufacturer.	
34.	The commercial invoice of API manufacturer specifies the batch number 00510911-12/078/2021 which have been tempered / changed by hand to convert 2021 into 2020. Provide actual copy of invoice along with written justifications for making changes in the invoice of API manufacturer.	
35.	Submit COA of batch number 00510911-12/078/2021.	
36.	The absorbance of standard and sample solution as submitted in validation studies are in the range of 0.5, while the absorance of the sample and standard solution (having same concentration) in stability studies is in the range of 0.7. Submit scientific justification how such significant change in the absorbance values can exist.	
37.	Justify the calculation of assay results using single value of sample and standard solution absorbance.	
38.	Submit proper BMR of the three stability batches since very brief document is submitted which does not specify performance of each and every step in the manufacturing.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

576.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 23-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of sections dated 21-02-2018. The letter specifies Tablet (General) section Revised.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29092: 13-10-2022
	Details of fee submitted	PKR 30,000/- : 11-08-2022
	The proposed proprietary name / brand name	**ZILSAR 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Azilsartan Medoxomil (as Potassium)…80mg
	Pharmaceutical form of applied drug	Angiotensin Receptor Blocker
	Pharmacotherapeutic Group of (API)	Uncoated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	Aziltec Tablet 40mg by Nabiqasim
	Name and address of API manufacturer.	AMI Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka- Padra, District-Vadodara Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	AMI Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka-Padra, District-Vadodara Gujarat, INDIA		
API Lot No.	AZP/50150820		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD-0088-26-SB	22PD-0089-27-SB	22PD-0090-28-SB
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product specific inspection for Empagin XR Tablet has been conducted on 05-12-2019 and the case was approved in 293rd meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Control Administration Gujrat State India valid till 17-04-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 01-12-2020 specifying 1.6Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:
Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

577.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt) Ltd Plot No. 241, Sector-24, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt) Ltd Plot No. 241, Sector-24, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 27-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 specifying Liquid Injection Vial/Ampoule (Steroid) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 30260: dated 05-11-2021
	Details of fee submitted	PKR 30,000/- Dated 28-05-2021
	The proposed proprietary name / brand name	**DEXACORT Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml injection contains: Dexamethasone (as sodium phosphate).....3.3mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Systemic corticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	25's:
	Proposed unit price	Rs. 1250
	The status in reference regulatory authorities	Dexamethasone Sodium Phosphate Injection (MHRA Approved)
	For generic drugs (me-too status)	Decadron Injection by OBS
	Name and address of API manufacturer.	Zhejiang Xianju Pharmaceutical Co Ltd. No 1, Xianyao Road, Xianju Taizhou Zhejiang China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Dexamethasone Injection from Hospira UK Limited
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Xianju Pharmaceutical Co Ltd. No 1, Xianyao Road, Xianju Taizhou Zhejiang China		
API Lot No.	150815		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-101	TB-102	TB-103
Batch Size	1 L	1 L	1 L
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	01-2017	01-2017	01-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China valid till 28-10-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice clared dated 28-11-2017 specifying dexamethasone base raw material
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit IR spectra for characterization of drug substance in section 3.2.S.3	Submitted
2.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	Submitted
3.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical studies are conducted	Dexamthasone Injection 3.3mg/ml by Hospira UK Limited. Batch No FDT258
4.	Submit valid GMP certificate of API manufacturer	Not submitted
5.	The submitted API clearance specify dexamethasone base while the product contains dexamtheasone sodium phosphate. Clarify	No justification is submitted
6.	The submitted API clearance is dated 28-11-2017 while your batches have been manufactured in January 2017	No justification is submitted
8.	Submit copy of BMR of all batches	Submitted.

Decision: Deferred for following:

- **Valid GMP certificate of API manufacturer.**
- **Clarification since the submitted API clearance specify dexamethasone base while the product contains dexamtheasone sodium phosphate.**
- **Clarification since the submitted API clearance is dated 28-11-2017 while the batches have been manufactured in January 2017.**

November 2022 – February 2023

578.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32472: 11-11-2022
	Details of fee submitted	PKR 30,000/- : 03-11-2022
	The proposed proprietary name / brand name	**FUNGOFINE 125mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Terbinafine HCL eq. to Terbinafine……125mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lamisil Tablet (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbisil Tablet by Saffron
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit complete clearance certificate for import of API since the submitted certificate only shows a table with product details however name of the firm importing the material and tracking ID etc are not shown.	Firm has submitted copy of clearance certificate dated 10-05-2022 specifying 6Kg Terbinfine HCl.
2.	Submit 6 month's stability study data since the submitted data is for 3 months only.	Firm has submitted 6th month stability study data.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

579.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32471,: 11-11-2022
	Details of fee submitted	PKR 30,000/- : 03-11-2022
	The proposed proprietary name / brand name	**FUNGOFINE 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Terbinafine HCL eq. to Terbinafine……250mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lamisil Tablet (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbisil Tablet by Saffron

	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit complete clearance certificate for import of API since the submitted certificate only shows a table with product details however name of the firm importing the material and tracking ID etc are not shown.	Firm has submitted copy of clearance certificate dated 10-05-2022 specifying 6Kg Terbinfine HCl.
2.	Submit 6 month's stability study data since the submitted data is for 3 months only.	Firm has submitted 6th month stability study data.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

580.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33963,: 24-11-2022
	Details of fee submitted	PKR 30,000/- : 22-11-2022
	The proposed proprietary name / brand name	**FUNGOFINE 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram contains: Terbinafine Hydrochloride……10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Lamisil Athletes Foot Cream (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbiderm cream by Atco
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit complete clearance certificate for import of API since the submitted certificate only shows a table with product details however name of the firm importing the material and tracking ID etc are not shown.	Firm has submitted copy of clearance certificate dated 10-05-2022 specifying 6Kg Terbinfine HCl.
2.	Submit 6 month's stability study data since the submitted data is for 3 months only.	Firm has submitted 6th month stability study data.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

581.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31336: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 15-10-2022
	The proposed proprietary name / brand name	**LINAMET 2.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of API manufacturer	Submitted.
2.	Submit evidence of import of API including clearance certificate.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 45,000 balance fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

582.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.**

	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1555: 17-01-2023
	Details of fee submitted	PKR 30,000/- : 07-01-2023
	The proposed proprietary name / brand name	**BROPIN 800mg/8ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml ampoule Contains: Ibuprofen…100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Ubrof Injection 800mg/8ml by Sami Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of API manufacturer	Submitted.
2.	Submit evidence of import of API including clearance certificate.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

583.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33021: 17-11-2022
	Details of fee submitted	PKR 30,000/- : 24-10-2022
	The proposed proprietary name / brand name	**TAMDOW-S 6/0.4 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer film-coated tablet contains: Solifenacin Succinate (as immediate release)…....6mg Tamsulosin HCl (as modified release)……..0.4mg
	Pharmacotherapeutic Group of (API)	Antimuscarinics with Alpha blockers

	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Tamsolin-S Tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit complete module 3.2.S from Alphamed Formulations for solifenacin as well as tamsulosin which are manufacturing the granules, since you have submitted module 3.2.S of basic raw material.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

584.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37087: 20-12-2022
	Details of fee submitted	PKR 30,000/- : 02-12-2022
	The proposed proprietary name / brand name	**PROZYN 20mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Oral Solution Contains: Fluoxetine HCl…20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**TGA** Australia Approved
	For generic drugs (me-too status)	Depricap syrup by Nabiqasim
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise label claim as per innovator's product along with submission of requisite fee.	Firm has revised the label claim as under: Each 5ml Oral Solution Contains: Fluoxetine (as HCl)…20mg

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 30,000 fee for revision in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

585.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2549: 26-01-2023
	Details of fee submitted	PKR 30,000/- : 11-01-2023
	The proposed proprietary name / brand name	**PREDHEAL Lotion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Methylprednisolone aceoponate…1mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**TGA** Australia Approved
	For generic drugs (me-too status)	Advacort Lotion by Atco
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

586.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4380: 15-02-2023
	Details of fee submitted	PKR 20,000/- : 23-04-2020 +

		PKR 10,000/- : 20-01-2023
	The proposed proprietary name / brand name	**NEUBROFEN 400mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Ibuprofen…400mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Aburid infusion by Vision pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
2.	Submit evidence of requisite manufacturing facility / section approval.	
3.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit report of verification studies of analytical method of drug substance.	
5.	Submit COA of reference standard / working standard actually used in the analysis of API.	
6.	Justify why your qualitative composition is different from innovator's product.	
7.	Submit pictorial evidence of the product against which pharmaceutical equivalence studies was conducted.	
8.	Provide details including batch number, manufacturer and country from where the product was procured for performing pharmaceutical equivalence studies.	
9.	Clarify why complete validation studies of the analytical method of the drug product was not conducted.	
10.	Submit evidence of import of API including clearance certificate.	
11.	Submit BMR of three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

587.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan**
	Name, address of Manufacturing site.	M/s Lucky Core Industries Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2734: 31-01-2023
	Details of fee submitted	PKR 30,000/- : 25-01-2023
	The proposed proprietary name / brand name	**LUMONT 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast as Sodium…4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Myteka sachet by Hilton
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit COA of relevant batch of API from both API manufacturer as well as drug product manufacturer.	
	Submit COA of reference standard / working standard actually used in the analysis of API.	
3.	Provide details about the particle size of API as well as mannitol used for the product development.	
4.	CDP studies show negligible drug release in 15 minutes while innovator's product literature reveals that the drug product release more than 85% within 10-15 inutes. Clarification is required in this regard.	
5.	Submit evidence of import of API including clearance certificate.	
6.	Submit BMR of three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

588.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36507: 15-12-2022
	Details of fee submitted	PKR 30,000/- : 06-12-2022
	The proposed proprietary name / brand name	**NEPOPT 0.3% Eye Drops Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Nepafenac…3mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory agent
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Ilvero ophthalmic suspension **Health Canada** Approved
	For generic drugs (me-too status)	Ilvero ophthalmic suspension by Novartis
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit preservative effectiveness studies	
3.	Justify why assay of benzalkonium chloride is not included in the drug product specification.	
4.	Submit valid GMP certificate of API manufacturer.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

589.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33635: 22-11-2022
	Details of fee submitted	PKR 75,000/- : 08-11-2022
	The proposed proprietary name / brand name	**DELA 450mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Delafloxacin Meglumine Eq. to Delafloxacin…450mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA

	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of your drug substance.	
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit signed and stamped stability study data of API from API manufacturer.	
4.	The review of innovator's product specify that the drug product release more than 85% in 10 minutes in 0.1 N HCl while your results show less than 70% results. Clarification is required in this regard.	
5.	Submit pictorial evidence of the reference pack used for PE and CDP studies.	
6.	Submit 6 month's stability study data.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

590.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33955: 08-12-2022
	Details of fee submitted	PKR 30,000/- : 21-11-2022
	The proposed proprietary name / brand name	**OSEMEZONE 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Delayed Release Tablet Contains: Naproxen…500mg Esomeprazole as Magnesium…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablet by Global
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm

1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Firm has submitted revised label claim as under, however fee is not submitted. Each Modified Release Tablet Contains: Naproxen (Enteric Coated)…500mg Esomeprazole Magnesium Trihydrate Eq. to Esomeprazole (Immediate Release Coat)…20mg
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Justify the use of reference standard from Surge for analysis of esomeprazole API.	Submitted.
4.	Specify details of manufacturer of the reference product against which pharmaceutical equivalence and CDP studies are conducted.	Submitted.
5.	Submit pictorial evidence of the reference pack used for PE and CDP studies.	Submitted.
6.	Submit valid GMP certificate of API manufacturer.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

591.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 856: 10-01-2023
	Details of fee submitted	PKR 75,000/- : 04-01-2023
	The proposed proprietary name / brand name	**AZILA 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Èach Tablet Contains: Azilsartan Medoxomil Potassium as Azilsartan Medoxomil…20mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Review of innovator's product suggest that the drug is unstable in aqueous solution of pH 1 and pH 7 and relatively stable from pH 3 to pH 5, while your CDP results show more than 85% results within 30 minutes. Clarification is required in this regard.	Submitted.
3.	Justify why the peak for fumaric acid is not observed during the stability studies since fumaric acid is included in the formulation.	Submitted.
4.	Azilsartan base is identified as an impurity in azilsartan medoxomil and the peak for azilsartan is also observed in HPLC analysis. Clarify why azilsartan base is not observed in any analysis during stability studies.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

592.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35343: 06-12-2022
	Details of fee submitted	PKR 30,000/- : 02-12-2022
	The proposed proprietary name / brand name	**VORTINE 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vortioxetine…10mg
	Pharmacotherapeutic Group of (API)	Serotonin modulators
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorneu Tablet by Hilton
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm

1.	Revise your label claim as per the innovator's product along with submission of requisite fee	Firm has submitted revised label claim as under, however fee is not submitted. Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. To Vortioxetine…10mg
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Justify the selection of dissolution medium for dissolution test, since CDP results reveal that more than 85% of drug content is released within 15 minutes. Clarify how your dissolution test is discriminatory in nature.	Submitted.
4.	Justify the use of UV method for dissolution test, Since the USFDA review of innovator's product reveals that HPLC method is used for dissolution test.	Submitted.
5.	Submit loan letter along with evidence of initimation submitted to PE&R Division.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

593.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35342: 06-12-2022
	Details of fee submitted	PKR 30,000/- : 02-12-2022
	The proposed proprietary name / brand name	**VORTINE 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vortioxetine…20mg
	Pharmacotherapeutic Group of (API)	Serotonin modulators
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorneu Tablet by Hilton
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee	Firm has submitted revised label claim as under, however fee is not submitted. Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. To Vortioxetine…20mg
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Justify the selection of dissolution medium for dissolution test, since CDP results reveal that more than 85% of drug content is released within 15 minutes. Clarify how your dissolution test is discriminatory in nature.	Submitted.
4.	Justify the use of UV method for dissolution test, Since the USFDA review of innovator's product reveals that HPLC method is used for dissolution test.	Submitted.
5.	Submit loan letter along with evidence of initimation submitted to PE&R Division.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

594.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2556: 26-01-2023
	Details of fee submitted	PKR 30,000/- : 20-01-2023
	The proposed proprietary name / brand name	**RESORIDE 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved

	For generic drugs (me-too status)	Prucalax Tablet by Kaizen
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Clarify the limit of content of succinic acid from 23.1% to 25.5% w/w while the limit of prucalopride assay is 98% to 102% w/w on anhydrous basis.	Submitted.
3.	Innovator's product has used drug substance with controlled particle size while your drug substance specifications oes not include any test for particle size distribution. Clarification is required in this regard.	Submitted.
4.	Justify the selection of dissolution medium for dissolution test, since CDP results reveal that more than 85% of drug content is released within 5 minutes. Clarify how your dissolution test is discriminatory in nature.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

595.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2557: 26-01-2023
	Details of fee submitted	PKR 30,000/- : 20-01-2023
	The proposed proprietary name / brand name	**RESORIDE 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…2mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Prucalax Tablet by Kaizen
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	Clarify the limit of content of succinic acid from 23.1% to 25.5% w/w while the limit of prucalopride assay is 98% to 102% w/w on anhydrous basis.	Submitted.
3.	Innovator's product has used drug substance with controlled particle size while your drug substance specifications oes not include any test for particle size distribution. Clarification is required in this regard.	Submitted.
4.	Justify the selection of dissolution medium for dissolution test, since CDP results reveal that more than 85% of drug content is released within 5 minutes. Clarify how your dissolution test is discriminatory in nature.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

596.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37708: 26-12-2022
	Details of fee submitted	PKR 30,000/- : 16-12-2022
	The proposed proprietary name / brand name	**VORFEXIN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vortioxetine…20mg
	Pharmacotherapeutic Group of (API)	Serotonin modulators
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorneu Tablet by Hilton
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm

1.	Revise your label claim as per the innovator's product along with submission of requisite fee	Firm has submitted revised label claim as under, however fee is not submitted. Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. To Vortioxetine…20mg
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Justify the selection of dissolution medium for dissolution test, since CDP results reveal that more than 85% of drug content is released within 15 minutes. Clarify how your dissolution test is discriminatory in nature.	Submitted.
4.	Justify the use of UV method for dissolution test, Since the USFDA review of innovator's product reveals that HPLC method is used for dissolution test.	Submitted.
5.	Submit loan letter along with evidence of initimation submitted to PE&R Division.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

597.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33636: 22-11-2022
	Details of fee submitted	PKR 30,000/- : 19-05-2021
	The proposed proprietary name / brand name	**SALZONE 2.5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Ampoule Contains: Sodium Chloride…0.9%
	Pharmacotherapeutic Group of (API)	Electrolyte solution
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Sodium Chloride Injection 0.9% w/v by Genix
	Proposed Pack size	As per SRO

EVALUATION OF DATA

Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
598.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33637: 22-11-2022
	Details of fee submitted	PKR 30,000/- : 19-05-2021
	The proposed proprietary name / brand name	**SALZONE 5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Ampoule Contains: Sodium Chloride…0.9%
	Pharmacotherapeutic Group of (API)	Electrolyte solution
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Sodium Chloride Injection 0.9% w/v by Genix
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
599.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33638: 22-11-2022
	Details of fee submitted	PKR 30,000/- : 02-06-2021
	The proposed proprietary name / brand name	**SALZONE 10ml Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml Ampoule Contains: Sodium Chloride…0.9%
	Pharmacotherapeutic Group of (API)	Electrolyte solution
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Sodium Chloride Injection 0.9% w/v by Genix
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

600.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swat Pharmaceuticals. Valley Road, sherari Gulkada No. 3, Saidu Sharif, Swat.**
	Name, address of Manufacturing site.	M/s Swat Pharmaceuticals. Valley Road, sherari Gulkada No. 3, Saidu Sharif, Swat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5258: 23-02-2023
	Details of fee submitted	PKR 30,000/- : 15-07-2022
	The proposed proprietary name / brand name	**SOCAM 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Inhouse
	The status in reference regulatory authorities	**Austria** Approved
	For generic drugs (me-too status)	Loxibar Tablet by Barret Hodgson
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report conducted within last three years.	
	Submit reference of specifications of the drug product, since you have mentioned "None" in section 1.5.6.	
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	

3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer.	
4.	Submit signed and stamped stability study data sheets of API from API manufacturer.	
5.	Justify why the verification studies does not include test for specificity and repeatability.	
6.	Submit raw data sheets for assay testing during stability studies	
7.	Submit analytical record for dissolution testing.	
8.	Submit GMP certificate of API manufacturer	
9.	Submit Documents for the procurement of API with approval from DRAP.	
10.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
11.	Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

601.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swat Pharmaceuticals. Valley Road, sherari Gulkada No. 3, Saidu Sharif, Swat.**
	Name, address of Manufacturing site.	M/s Swat Pharmaceuticals. Valley Road, sherari Gulkada No. 3, Saidu Sharif, Swat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5257: 23-02-2023
	Details of fee submitted	PKR 30,000/- : 15-07-2022
	The proposed proprietary name / brand name	**SWAFLU 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluconazole…150mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Flozex Capsule by Martin Dow
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report conducted within last three years.	
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	

3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer.	
4.	Justify the adaptation of JP method for your drug product since JP method is for 50mg and 100mg capsule while your applied formulation is 150mg capsule.	
5.	Justify why your dissolution test as well as assay test is different from JP.	
6.	Justify why the verification studies does not include test for specificity and repeatability.	
7.	Submit GMP certificate of API manufacturer	
8.	Submit Documents for the procurement of API with approval from DRAP.	
9.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
10.	Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

602.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3530: 07-02-2023
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**ONDEX 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Ondansetron HCl……8mg
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Zofran Tablet (**USFDA** Approved and discontinued for reasons other than safety and efficacy as per Drugs@FDA database)
	For generic drugs (me-too status)	Onset 8mg Tablet by Pharmedic
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of requisite manufacturing facility / section approval of drug product manufacturer.	

2.	Submit GMP certificate / inspection report conducted within last three years.	
3.	Revise label claim as per innovator's product along with submission of 30,000 fee for correction of formulation / label claim.	
4.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
5.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer.	
6.	Submit master formulation in section 3.2.P.1.	
7.	Justify the performance of CDP studies only in acidified water pH 6.0.	
8.	Justify how drug dissolution of a single tablet in a basket at a later time point is less than the dissolution at earlier time point.	
9.	Submit batch formula in section 3.2.P.3.2.	
10.	Justify why the calculation formula for dissolution test in your method is entirely different from that specified in USP.	
11.	Submit stability study data of the drug product in section 3.2.P.8.3 as per guidance document in proper sequence for each time point along with separators i.e. summary sheet, rawa data sheet, relevant analytical record.	
12.	Submit data as per 6 points checklist as specified in the CTD guidance document.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

603.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31976: 04-11-2022
	Details of fee submitted	PKR 75,000/- : 28-10-2022
	The proposed proprietary name / brand name	**ONDONIX 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each orally disintegrating tablet contains: Ondansetron……4mg
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP

	The status in reference regulatory authorities	Zofran ODT Tablet (**USFDA** Approved and discontinued for reasons other than safety and efficacy as per Drugs@FDA database)
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer.	Submitted
2.	Submit COA of relevant batch of API from both API manufacturer and drug product manufacturer.	Submitted
3.	The innovator's product used ondansetron base while your module 3.2.S as well as COA of API specifies that you have used ondansetron HCl. Clarify how your product could be considered as genric product.	We acknowledge the discrepancy in developing the product in ondansetron HCL intead of base and we are currently implementing the corrective measures to ensure compliance with reference product. We will submit the data of said product after its correction is done.

Decision: Deferred for submission of data of revised batches of drug product manufactured as per the innovator's product.

604.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10 Quaid-e-Azam Industial Area Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10 Quaid-e-Azam Industial Area Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4045: 13-02-2023
	Details of fee submitted	PKR 30,000/- : 26-01-2023
	The proposed proprietary name / brand name	**JOXETINE 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Fluoxetine HCL eq. to Fluoxetine……20mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Rise Capsule by Werrick
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report of drug product manufacturer.	

2.	Clarify how specificity test was performed during verification studies of analytical method of drug substance.	
3.	Your master formulation specifies 20mg fluoxetine hydrochloride per capsule. While your label claim specifies 20mg Fluoxetine base per capsule. Justify how your formulation supports your label claim.	
4.	The chromatograms for assay specify the run time for 35 minutes, while consecutive HPLC run for standard are acquired after 30 – 32 minutes. Justify how HPLC analysis of subsequent standard can be performed even prior to the completion of initial run.	
5.	The USP specifies that for calculation of assay, the formula also utilizes the ratio of molecular weight of fluoxetine and fluoxetine HCl (i.e. 309.33 / 345.79 = 0.89), while your analysis and raw data sheets does not use this ratio to calculate the assay results. Clarify how your method can be considered compliant to USP and further how your results can be considered accurate.	
6.	If USP specified formula is used, the assay result of your analysis falls below 90% at all time points. Clarification is required in this regard.	
7.	The dissolution analysis as per USP is to be performed using UV detector at 226nm while your analysis has been performed at 227nm. Clarification is required in this regard.	
8.	The HPLC chromatograms of standard run for assay test and sample run for dissolution test are exactly same and also conducted at exactly same time having same date and time acquired. Clarification is required in this regard.	
9.	Submit Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
10.	Submit clearance certificate / ADC cleared commercial invoice as evidence of import of drug substance from the specified source.	
11.	You have been allowed by DRAP Lahore office to import 100gm Fluoxetine HCl on 20-03-2020. While as per your batch sizes more than 350gm API is required to manufacture batches of specified batch size. Clarification is required in this regard.	
12.	Submit Batch Manufacturing Record of three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

605.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34815,: 01-12-2022
	Details of fee submitted	PKR 30,000/- : 24-11-2022
	The proposed proprietary name / brand name	**TERB-C Topical Solution 1% w/w**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram contains: Terbinafine Hydrochloride……10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Lamisil 1% cutaneous solution (**Sweeden** Approved)
	For generic drugs (me-too status)	Terbisil Lotion by Saffron
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
2.	The applied formulation is applied and approved by reference regulatory authorities as 1% w/w topical solution while your master formulation specifies purified water as "Q.S". Clarification is required in this regard.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

606.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad.**
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2253,: 24-01-2023
	Details of fee submitted	PKR 30,000/- : 16-01-2023
	The proposed proprietary name / brand name	**TERBIPEARL 1% w/w Lotion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram contains: Terbinafine Hydrochloride……10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Lamisil 1% cutaneous solution (**Sweeden** Approved)
	For generic drugs (me-too status)	Terbisil Lotion by Saffron
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of required manufacturing facility / section approval from Licensing Division, since your letter for renewal of DML does not specify Lotion (General) section.	Our steroid Lotion section was approved in 2011 since then we are manufacturing general product in the same section like scabipearl lotion clindapearl lotion and Dixidil lotion.
2.	Submit GMP certificate of the drug product manuafcturer.	Submitted
3.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
4.	Clarify how specificity test was performed in analytical method verification studies. Further also justify your test in the light of ICH Q2 guidelines.	No clarification is submitted.
5.	Specify why complete testing is not performed in pharmaceutical evaluation studies.	Submitted.
6.	Justify why you have not included test of pH in your drug product specifications.	pH test is now included in specification
7.	Submit evidence of import of API (AD attested invoice or clearance certificate), since you have only submitted copy of commercial invoice without clearance from DRAP.	Firm has submitted copy of clearance certificate dated 07-06-2021.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

607.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caliph Pharmaceuticals (Pvt) Ltd Plot No. 17, Special Industrial Zone (EPZ), Risalpur**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd Plot No. 17, Special Industrial Zone (EPZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3120,: 02-02-2023
	Details of fee submitted	PKR 30,000/- : 01-02-2023
	The proposed proprietary name / brand name	**LAMICAL 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram contains: Terbinafine Hydrochloride……10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Lamisil Athletes Foot Cream (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbiderm cream by Atco

	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

608.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4216: 14-02-2023
	Details of fee submitted	PKR 30,000/- : 28-11-2022
	The proposed proprietary name / brand name	**SILO-M XR 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin … 50mg Metformin HCl USP ……. 500mg (as extended release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Sita Met XR Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
609.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4215: 14-02-2023
	Details of fee submitted	PKR 30,000/- : 28-11-2022
	The proposed proprietary name / brand name	**SILO-M XR 100/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin … 100mg Metformin HCl USP ……. 1000mg (as extended release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Sita Met XR Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

610.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK**
	Name, address of Manufacturing site.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5251,: 23-02-2023
	Details of fee submitted	PKR 30,000/- : 15-03-2022
	The proposed proprietary name / brand name	**LODAL PLUS 37.5/325 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Tramadol Hcl…37.5mg Paracetamol…325mg
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
Evaluation by PEC[3] :		

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise label claim as per innovator's product along with submission of fee.	

2.	Submit GMP certificate of the drug product manuafcturer.	
3.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
5.	Submit details against which CDP and PE studies are conducted	
6.	Submit GMP certificate of the API manuafcturer.	
7.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

611.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34066,: 25-11-2022
	Details of fee submitted	PKR 75,000/- : 23-09-2022
	The proposed proprietary name / brand name	**PRUCILO 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of the drug product manuafcturer.	Submitted.
2.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted.
4.	Submit details against which CDP and PE studies are conducted	Submitted.
5.	Submit GMP certificate of the API manuafcturer.	Submitted.
6.	Submit evidence of purchase of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

612.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1730,: 18-01-2023
	Details of fee submitted	PKR 75,000/- : 29-12-2022
	The proposed proprietary name / brand name	**PRUCILO 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…2mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of the drug product manuafcturer.	Submitted.
2.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted.
4.	Submit details against which CDP and PE studies are conducted	Submitted.
5.	Submit GMP certificate of the API manuafcturer.	Submitted.
6.	Submit evidence of purchase of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

613.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34703,: 30-11-2022
	Details of fee submitted	PKR 75,000/- : 23-09-2022
	The proposed proprietary name / brand name	**AZILSARTRAN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Azilsartan Medoxomil…20mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of the drug product manuafcturer.	Submitted.
2.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted.
4.	Submit details against which CDP and PE studies are conducted	Submitted.
5.	Submit GMP certificate of the API manuafcturer.	Submitted.
6.	Submit evidence of purchase of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

614.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34702,: 30-11-2022
	Details of fee submitted	PKR 75,000/- : 23-09-2022
	The proposed proprietary name / brand name	**AZILSARTRAN 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Azilsartan Medoxomil…80mg
	Pharmacotherapeutic Group of (API)	Antihypertensive

	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate of the drug product manuafcturer.	Submitted.
2.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted.
4.	Submit details against which CDP and PE studies are conducted	Submitted.
5.	Submit GMP certificate of the API manuafcturer.	Submitted.
6.	Submit evidence of purchase of API.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

615.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 486,: 05-01-2023
	Details of fee submitted	PKR 30,000/- : 13-12-2022
	The proposed proprietary name / brand name	**DIAZEN 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Desloratadine…5mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per innovator's product along with submission of requisite fee	

2.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
4.	Submit details against which CDP and PE studies are conducted	
5.	Submit GMP certificate of the API manuafcturer.	
6.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

616.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34287,: 28-11-2022
	Details of fee submitted	PKR 30,000/- : 28-09-2022
	The proposed proprietary name / brand name	**AVTOR 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Atorvastatin as Calcium Trihydrate…40mg
	Pharmacotherapeutic Group of (API)	Antihyperlipidemic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

617.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mcolson Research Laboratories Pvt Ltd.**

		26 km Lahore-Sheikhupura Road, Sheikhupura
	Name, address of Manufacturing site.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5489,: 27-02-2023
	Details of fee submitted	PKR 30,000/- : 20-01-2023
	The proposed proprietary name / brand name	**APRIN 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Apremilast…30mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

618.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1180: 13-01-2023
	Details of fee submitted	PKR 30,000/- : 15-11-2022
	The proposed proprietary name / brand name	**METFORMIN HCl 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hcl…500mg

	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

619.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31570: 03-11-2022
	Details of fee submitted	PKR 30,000/- : 11-10-2022
	The proposed proprietary name / brand name	**JENSOLOR 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Drugs for constipation
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	

4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

620.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2738: 31-01-2023
	Details of fee submitted	PKR 30,000/- : 02-12-2022
	The proposed proprietary name / brand name	**LINTOL Opthalmic Suspension Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Loteprednol Etabonate…5mg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

The applied formulaton is already registered in the name of the firm.
Brand Name: Predbon Ophthalmic Suspension 0.5% w/v
Reg No: 097215

Decision: Registration Board keeping in view the fact that applied formulation is already registered in the name of the firm, disposed off the application.

621.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35495: 07-12-2022
	Details of fee submitted	PKR 30,000/- : 04-10-2022
	The proposed proprietary name / brand name	**PHYTONADIONE 10mg/1ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Vitamin K1…10mg
	Pharmacotherapeutic Group of (API)	Vitamin

	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

b. Deferred cases of local manuafcturing

622.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12293: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFEZOL IV Infusion 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Metronidazole……500mg

	Pharmaceutical form of applied drug	Clear colorless to pale yellow solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Anti bacterials for systemic use: imidazole derivatives
	Reference to Finished product specifications	BP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Otsuzol Infusion by Otsuka Pharma
	Name and address of API manufacturer.	Hubei Hongyuan Pharmaceutical Technology Co., Ltd. No. 3, Hongyuan Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Otsuzol Injection by Otsuka Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance.

		Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hubei Hongyuan Pharmaceutical Technology Co., Ltd. No. 3, Hongyuan Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province China.		
API Lot No.	0182110063		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	133 liters	133 liters	133 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	27-01-2022	27-01-2022	27-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HB20180424) of Hubei Hongyuan Pharmaceutical Technology Co., Ltd. issued by China Food and Drug Administration. The certificate is valid till 30-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 2Kg Metronidazole.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify why the test of sulphated ash is not specified in the drug substance specification although this tet is recommended in BP monograph.	*Sulphated ash test was not mentioned in BP 2022.* **Firm has not submitted any relevant response.**
2.	Provide COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	**Firm has not submitted any response.**
3.	Provide description of pharmaceutical development as per the CTD guidance	*Copy attached for master formulation and method of manufacturing in detail and proper information*

	document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".	*as per the CTD guidance regarding justification of formulation. And method of manufacturing.* **Firm has not submitted any relevant response.**
4.	You have mentioned "not applicable" for drug substance in section 3.2.P.2.1.1. Justify why you have mentioned not applicable and also provide information as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."	*The compatibility of the drug substance with excipients listed in 3.2.P.1 should be discussed. Additionally, key physicochemical characteristics (e.g., water content, solubility, and particle size distribution, polymorphic or solid state form) of the drug substance that can influence the performance of the drug product should be discussed. For combination products, the compatibility of drug substances with each other should be discussed as per the CTD guidance.* **Firm has not submitted any relevant response.**
5.	Provide information regarding excipients added in the formulation in section 3.2.P.2.1.2.	*The choice of excipients listed in 3.2.P.1, their concentration, and their characteristics that can influence the drug product performance should be discussed relative to their respective functions.* **Firm has not submitted any relevant response.**
6.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*We have studied our comparator product & found that they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity.* **Firm has not submitted any relevant response.**
7.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
8.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
9.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
10.	Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.	**Firm has not submitted any response.**
11.	Justify why the assay test mentioned in your analytical method is completely different from that spcifed in latest edition of BP monograph in terms of sample solution preparation, media in which sample solution	*Our analytical method is BP 2022* **Firm has not submitted any relevant response.**

	is to be diluted and the calculation formula and procedure.	
12.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies of the analytical method of drug product in section 3.2.P.5.3.* **Firm has submitted process validation report instead of analytical method verification.**
13.	Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6 instad of providing COA of the drug substance commercial lot.	**Firm has submitted COA of the drug substance commercial lot as COA of working standard.**
14.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
15.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
16.	Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.	**Firm has not submitted any response.**
17.	Provide information in section 3.2.P.8.2 as per the CTD guidance document since you have mentioned "not applicable" in this section.	**Firm has not submitted any response.**
18.	The assay results of batch T-001 at batch analysis stage (section 3.2.P.5.4) shows 100% results while the initial stability results (section 3.2.P.8.3) performed on the same day show 104%. Justify how significant difference in results exists on the same date.	*Assay limits are 95-110% in BP 2022.* **Firm has not submitted any relevant response.**
19.	The stability data sheet for batch T001 shows that the assay result at initial time point for accelerated and real time studies are different. Clarification is required in this regard.	**Firm has not submitted any response.**
20.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*Bottles placed in stability chamber were with simple cap not with Euro CAP.*
21.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*65 bottles in real stabilty chamber.* *80 bottles in accelerated stabilty chamber.*
22.	Justify why the assay testing procedure adopted during the stability studies is completely different from BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **Firm has not submitted any relevant response. The assay method of the firm is different from BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.**

23.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
24.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**

Decision of 323rd meeting of RB:

Deferred for following submissions:

- Scientific justification why the test of sulphated ash is not specified in the drug substance specification although this tet is recommended in BP monograph.
- COA of reference standard actually used in the analysis of drug substance.
- Description of pharmaceutical development of the applied product as per the CTD guidance document.
- Submission of details of drug substance in section 3.2.P.2.1.1 of Module 3.
- Submission of information regarding excipients added in the formulation in section 3.2.P.2.1.2.
- Pharmaceutical equivalence studies against the innovator's product.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Submission of details of excipients used in the formulation in section 3.2.P.4.
- Scientific justification for performing assay test of drug product which is completely different from that spcifed in latest edition of BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.
- Report of verification studies of the analytical method of drug product in section 3.2.P.5.3.
- Scientific justification for using commercial lot of API as working standard without any standardization.
- Submission of requisite information in section 3.2.P.8.1 and 3.2.P.8.2 as per the CTD guidance document.
- Scientific justification for the assay results of batch T-001 at batch analysis stage (section 3.2.P.5.4) which shows 100% results while the initial stability results (section 3.2.P.8.3) performed on the same day show 104%.
- Scientific justification for having different results at accelerated and real time conditions for batch T001.
- Scientific justification why test of water loss is not performed during the stability studies.
- Batch size of drug product stability batches in terms of no. of units.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Scientific justification why the test of sulphated ash is not specified in the drug substance specification although this tet is recommended in BP monograph.	Firm has submitted complete method of testing from API manufacturer which includes test for sulphated ash.
2.	COA of reference standard actually used in the analysis of drug substance.	Firm has submitted COA of working standard.
3.	Description of pharmaceutical development of the applied product as per the CTD guidance document.	Firm has submitted report of pharmaceutical development.
4.	Submission of details of drug substance in section 3.2.P.2.1.1 of Module 3.	Firm has submitted details of drug substance in 3.2.P.1.1 section
5.	Submission of information regarding excipients added in the formulation in section 3.2.P.2.1.2.	Firm has submitted information regarding excipients.

6.	Pharmaceutical equivalence studies against the innovator's product.	Firm has submitted pharmaceutical equivalence studies against Flagyl infusion.
7.	Submission of microbiological attributes of the drug product in section 3.2.P.2.5.	Firm has submitted microbiological attributes of the drug product in section 3.2.P.2.5.
8.	Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.	Firm has submitted process validation procotocols and report of performance by Ashrafsons
9.	Submission of details of excipients used in the formulation in section 3.2.P.4.	Firm has submitted details of excipients in section 3.2.P.4
10.	Scientific justification for performing assay test of drug product which is completely different from that spcifed in latest edition of BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.	Firm has submitted raw data sheets as well as detailed method along with verification studies report as per BP monograph. Report of testing at 12, 18 and 24 months as per BP is also submitted.
11.	Report of verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted report of verification studies of the analytical method of drug product in section 3.2.P.5.3.
12.	Scientific justification for using commercial lot of API as working standard without any standardization.	Firm has submitted COA of working standard of API.
13.	Submission of requisite information in section 3.2.P.8.1 and 3.2.P.8.2 as per the CTD guidance document.	Firm has submitted details in section 3.2.P.8.1 and 3.2.P.8.2.
14.	Scientific justification for the assay results of batch T-001 at batch analysis stage (section 3.2.P.5.4) which shows 100% results while the initial stability results (section 3.2.P.8.3) performed on the same day show 104%.	We have performed batch analysis testing at the batch release stage. Another testing was also performed before placing the batches in stability chamber. That test was used as initial time point for stability studies.
15.	Scientific justification for having different results at accelerated and real time conditions for batch T001.	Th initial stability results are same, the mistake was due to different results at batch release and initial stability since two different tests were performed.
16.	Scientific justification why test of water loss is not performed during the stability studies.	Firm has submitted report of water loss studies.
17.	Batch size of drug product stability batches in terms of no. of units.	1330 vial each

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7,500 fee for correction in specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
623.	M/s McOlson Research	Esonap 500/20mg Tablet Each Double Core Tablet	Form 5D Dy No. 1458	Approved by USFDA

	Laboratories (Pvt) Ltd Plot No 2, M-2, Pharmazone 26 KM Lahor Sharikpur Road Sheikhupura.	Contains: Naproxen (as enteric coated inner core)…500mg Esomeprazole (as magnesium trihydrate film coated immediate release outer core)……20mg (NSAID + PPI) In-house specifications	15-01-2011 PKR. 8,000/- 13-01-2011 + PKR 12000 24-11-2014 As per SRO	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-06-2022.

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Esomeprazole:** Metrochem API Pvt Ltd Unit-I Plot No. 62/C/6, Pipeline Road, Phase-I IDA Jeedimetla Mandal, Malkajgiri Telangana India. **Naproxen:** Divi's Laboratories Limited, Unit-II, Annavaram Visakhapatnam Andhra Pradesh India		
API Lot No.	**Esomeprazole:** ESM/1906234 **Naproxen:** 2-M-B-2050818		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	ENS-PB-02	ENS-PB-03	ENS-PB-04
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	02-11-2019	02-11-2019	02-11-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Detox Tablet, for which the inspection was conducted on 31-12-2021 & 11-01-2021 and the report was presented in 293rd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Esomeprazole:** Firm has submitted stability study data of 3 batches of drug substance as per refrigerating conditions **Naproxen:**

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Esomeprazole:** Firm has submitted copy of GMP certificate issued by DCA Telangana India issued on 22-04-2020 **Naproxen:** Firm has submitted copy of GMP certificate dated 26-06-2021 issued by DCA Government of Andhra Pradesh.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole:** Firm has submitted copy of commercial invoice cleared dated 02-07-2019 specifying 15Kg API. The invoice is cleared by AD (I&E) DRAP. **Naproxen:** Firm has submitted copy of commercial invoice cleared dated 12-02-2019 specifying 6.5Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		
• CDP studies are not provided by the firm		
Decision of 333rd meeting of RB: Deferred for submission of comparative dissolution profile (CDP) studies with innovator / reference product.		
Response by the firm: Firm has submitted result of CDP studies conducted against innovator's product Vomovo Tablet		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

624.	Name, address of Applicant / Marketing Authorization Holder	**M/s Radiant Pharma (Pvt) Ltd. 43-E, Sunder Industrial Estate, Sunder Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) 9.5 K.M. Sheikhupura Road, Lahore.

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-07-2019 issued on the basis of inspection dated 28-02-2019.
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 9833 dated 18-04-2022
	Details of fee submitted	PKR 50,000/- Dated 10-03-2021
	The proposed proprietary name / brand name	**C-LEXIN 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefalexin as Monohydrate…500mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosposin
	Reference to Finished product specifications	BP
	Proposed Pack size	1x12's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ceporex Capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited 34-KM, Ferozepur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real

		time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Ceporex Capsule of GSK Firm has submitted results of CDP for their product against Ceporex Capsule of GSK
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited 34-KM, Ferozepur Road Lahore.		
API Lot No.	00214/023/2019		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	17-02-2020	20-02-2020	24-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	
2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	
3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	
4.	Submit evidence of approval of required section from Licensing Division DRAP.	
5.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
6.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
7.	Submit COA of reference standard actually used in the analysis of drug substance.	
	Justify why the composition is qualitatively different from the innovator's product	
11.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
14.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
15.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 331st meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	Firm has submitted 25000 fee
2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	Firm has revised Form 5F
3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-04-2022.
4.	Submit evidence of approval of required section from Licensing Division DRAP.	Firm has submitted copy of letter of renewal of DML dated 04-07-2022

		specifying Capsule (Cephalosporin) section.
5.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted by the firm
6.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted by the firm
7.	Submit COA of reference standard actually used in the analysis of drug substance.	Submitted by the firm
	Justify why the composition is qualitatively different from the innovator's product	Firm has sumitted evidence of MHRA approved product having similar qualitative composition
11.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	Submitted by the firm
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Submitted by the firm
14.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 18-11-2022.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of sales tax invoice dated 19-05-2019 specifying 25Kg API.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

625.	Name, address of Applicant / Marketing Authorization Holder	**M/s Radiant Pharma (Pvt) Ltd. 43-E, Sunder Industrial Estate, Sunder Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) 9.5 K.M. Sheikhupura Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-07-2019 issued on the basis of inspection dated 28-02-2019.
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 9834 dated 18-04-2022
	Details of fee submitted	PKR 50,000/- Dated 23-04-2020

	The proposed proprietary name / brand name	**Z-PLUS IM/IV 2gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Injection Contains: Cefoperazone Sodium Eq. to Cefoperazone…1000mg Sulbactam Sodium Eq. to Sulbactam…1000mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosposin
	Reference to Finished product specifications	
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for injection **Slovakia:** Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	Cebac injection by Bosch
	Name and address of API manufacturer.	Suzhou Dawnrays Pharmaceutical Co Ltd. No 22, Tianling Road, Wuzhong Economic development District Suzhou Jiangsu Yangkou Chemical Industrial Park Ruding County Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Cefmax Injection of Kurative Pharma
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Suzhou Dawnrays Pharmaceutical Co Ltd. No 22, Tianling Road, Wuzhong Economic development District Suzhou Jiangsu Yangkou Chemical Industrial Park Ruding County Jiangsu China		
API Lot No.			
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	9500 Vials	9500 Vials	9500 Vials
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	03-12-2018	03-12-2018	03-12-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	
2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	

3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	
4.	Submit evidence of approval of required section from Licensing Division DRAP.	
5.	Justify the claim of USP specifications while no USP monograph exist for this product.	
6.	Justify the use of drug substance which does not comply JP specifications, since the product monograph exists in JP.	
7.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
8.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
9.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	
10.	Submit COA of reference standard actually used in the analysis of drug substance.	
11.	Submit stability study data of three batches of API since stability conditions of the already submitted stability data seems edited.	
12.	Submit pharmaceutical equivalence studies against the innovator product.	
13.	Submit compatibility studies along with recommended diluent	
14.	Justify the finished product specifications as per JP monograph while the specifications of drug substance are different from the limits defined by JP.	
15.	The analytical method of drug product in section 3.2.P.5.2 specifies assay method for cefoperazone only. Clarification is required in this regard.	
16.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	
17.	Justify the significant change (i.e. more than 5% change) in assay result of both cefoperazone as well as sulbactam batch No. 004 during the accelerated stability studies.	
18.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
19.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
20.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 331st meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	Firm has submitted 25,000 fee

2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	Firm has submitted revised form 5F
3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-04-2022.
4.	Submit evidence of approval of required section from Licensing Division DRAP.	Firm has submitted copy of letter of renewal of DML dated 04-07-2022 specifying Dry powder injection (Cephalosporin) section.
5.	Justify the claim of USP specifications while no USP monograph exist for this product.	No justification submitted
6.	Justify the use of drug substance which does not comply JP specifications, since the product monograph exists in JP.	No justification submitted
7.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted by the firm
8.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted by the firm
9.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	Firm has submitted COA of batch 1911405107
10.	Submit COA of reference standard actually used in the analysis of drug substance.	Submitted by the firm
11.	Submit stability study data of three batches of API since stability conditions of the already submitted stability data seems edited.	Submitted by the firm
12.	Submit pharmaceutical equivalence studies against the innovator product.	Not submitted
13.	Submit compatibility studies along with recommended diluent	Submitted by the firm
14.	Justify the finished product specifications as per JP monograph while the specifications of drug substance are different from the limits defined by JP.	No justification submitted
15.	The analytical method of drug product in section 3.2.P.5.2 specifies assay method for cefoperazone only. Clarification is required in this regard.	Firm has submitted revised method
16.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	Submitted by the firm
17.	Justify the significant change (i.e. more than 5% change) in assay result of both cefoperazone as well as sulbactam batch No. 004 during the accelerated stability studies.	No justification submitted
18.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Firm has now submitted stability data sheets of different batches
19.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Valid GMP certificate is not submitted
20.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice cleared dated 21-01-2020
Decision: A Approved with Innovator's specifications.		

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
626.	Name, address of Applicant / Marketing Authorization Holder	**M/s Radiant Pharma (Pvt) Ltd. 43-E, Sunder Industrial Estate, Sunder Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) 9.5 K.M. Sheikhupura Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-07-2019 issued on the basis of inspection dated 28-02-2019.
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 10053 dated 20-04-2022
	Details of fee submitted	PKR 50,000/- Dated 05-11-2020
	The proposed proprietary name / brand name	**ROFANAC 75mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule Contains: Diclofenac sodium…75mg
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	In house specs
	Proposed Pack size	3ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Dicloran injection by Sami
	Name and address of API manufacturer.	Shanghai Jindi Jiuzhou Pharmaceutical Anyang Co. Ltd Bianque Road Industrial Park of Tangyin Anyang City China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Dicloran Injection of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA			
Manufacturer of API	Shanghai Jindi Jiuzhou Pharmaceutical Anyang Co. Ltd Bianque Road Industrial Park of Tangyin Anyang City China.		
API Lot No.	20191202		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	09-03-2020	09-03-2020	09-03-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	
2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	
3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	
4.	Submit evidence of approval of required section from Licensing Division DRAP.	
5.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
6.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
7.	Submit COA of reference standard actually used in the analysis of drug substance.	
8.	Justify why the qualitative composition of applied product is different from that of innovator's product	
9.	Submit pharmaceutical equivalence studies against the innovator product.	
10.	The analytical method of drug product in section 3.2.P.5.2 specifies UV method for assay testing of drug product. Clarification is required in this regard.	
11.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	
12.	Justify the consistent increase in assay value i.e. from 100% at initial time point to 104% at 6th month for all batches.	
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
14.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
15.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 331st meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit Balance fee i.e. 25,000 since only 50,000 fee is submitted.	Firm has submitted 25,000 fee
2.	Name of the applicant is mentioned as Neutro Pharma, while fee is submitted by Radiant Pharma. Correction is required in Form 5F along with full fee of registration.	Firm has submitted revised form 5F
3.	Submit GMP certificate / inspection report of the drug product manufacturer conducted within a period of last 3 years	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-04-2022.
4.	Submit evidence of approval of required section from Licensing Division DRAP.	Firm has submitted copy of letter of renewal of DML dated 04-07-2022 specifying liquid injection ampoule / vial (General) section.
5.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted by the firm
6.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted by the firm
7.	Submit COA of reference standard actually used in the analysis of drug substance.	Submitted by the firm
8.	Justify why the qualitative composition of applied product is different from that of innovator's product	No justification is submitted
9.	Submit pharmaceutical equivalence studies against the innovator product.	Firm has submitted pharmaceutical equivalence against Dicloran injection
10.	The analytical method of drug product in section 3.2.P.5.2 specifies UV method for assay testing of drug product. Clarification is required in this regard.	No clarification is submitted instead a new method is submitted
11.	Submit comprehensive report of validation studies of the analytical method of drug product since you have submitted raw data without any summarized results.	Submitted by the firm
12.	Justify the consistent increase in assay value i.e. from 100% at initial time point to 104% at 6th month for all batches.	No justification is submitted
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Not submitted
14.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
627.	M/s Scilife Pharma (Pvt.) Ltd Plot FD-57/58-A2 Korangi Creek Industrial Park Karachi	Eflozin 12.5/850 mg Tablet Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 37405 12-11-2018 PKR. 50,000/- 12-11-2018 As per SRO	Approved by EMA Firm has submitted copy of GMP certificate dated 07-03-2023 based on inspection conducted on 22-02-2023.

Date of submission of stability study data: 19-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park Fumeng County Liaoning Province China **Metformin:** Shouguang Fukang Pharmaceutical Co., Ltd North-east of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province China		
API Lot No.	**Empagliflozin:** E20190920-D02-E06-01 **Metformin:** A-32612004031		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	119B20	120B20	121B20
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	07-09-2020	07-09-2020	07-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Eflozin Tablet, for which the inspection was conducted on 27-09-2019 and the report was presented in 292nd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer

4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone II conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 20-12-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by CFDA China valid till 22-11-2021
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 30-01-2020 specifying 10Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 16-06-2020 specifying 3000Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xenglu-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Submit stability study data of empagliflozin API as per zone IV-A conditions.

Decision of 333rd meeting of RB:

Deferred for following submissions:

- Stability study data of empagliflozin API as per zone IV-A conditions.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Response by the firm:

- Firm has submitted stability study data of empagliflozin API as per zone IV-A conditions.
- However, GMP certificate of API manufacturer is not submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
628.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form and Strength	Glusimet XR 100/1000 mg Tablets
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate as Monohydrate…100mg Metformin HCl (extended release)…1000mg
	Dairy No. date of R &I fee	Dy No. 14973: 25.04.2018 PKR 20,000/-: 25.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	The firm has claimed manufacturer's specifications.
	Pack size and Demand Price	5x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	JANUMET XR 50/1000 sitagliptin (as phosphate monohydrate)/metformin hydrochloride 50 mg/1000 mg extended release tablet. TGA approved
	Me-too-status	Tagipmet XR 100/500 Tablet. Reg. No. 84651
	GMP Status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remark of the Evaluator	• The firm was asked to submit stability data of three batches conducted in Zone IV-A. The firm did not submit the same.

Decision of 290th meeting of Registration Board: Deferred for submission of stability data of of product as per decision of Registration Board.

Date of submission of stability study data: 01-03-2021

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin:** Zhejiang Yongtai Pharmaceutical Co td. Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone Linhai City, Zhejiang Province China **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Sitagliptin:** 1827-0001-19080 **Metformin:** MEF19081813		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	013B20	014B20	015B20
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	20-04-2020	20-04-2020	20-04-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Eflozin Tablet, for which the inspection was conducted on 27-09-2019 and the report was presented in 292nd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Sitagliptin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone II conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** Firm has submitted copy of GMP certificate issued by CFDA China valid till 03-05-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin:** Firm has submitted copy of commercial invoice cleared dated 30-08-2019 specifying 150Kg API. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 30-09-2019 specifying 1500Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Tagipmet-XT tablet of Highnoon Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		

• Submit stability study data of metformin API as per zone IV-A conditions.
Decision of 333rd meeting of RB: Deferred for following submissions: • Stability study data of empagliflozin API as per zone IV-A conditions. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
Response by the firm: • Firm has submitted stability study data of empagliflozin API as per zone IV-A conditions. • Firm has submitted copy of GMP certificate of API manufacturer of metformin issued by Food & Drugs Control Administration valid till 20-06-2026, However, GMP certificate of API manufacturer of sitagliptin is not submitted from relevant regulatory authority.
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

629.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2257: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……20mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
API Lot No.	AFPH007658

Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RLD-001	RLD-002	RLD-003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	03-06-2022	03-06-2022	03-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	Justify the results of CDP studies in which the	

	drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
6.	Provide BMR for the three stability batches.	

Decision of 330th meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	Crystalline Form A
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	Submitted by the firm
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	For the performance of CDP studies two standard solutions are prepared by same media and established dissolution method submitted is with same media which show release more than 85% in 30 mins. Updated CDP report which is calculated against established method standard solution show result less than release.
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	Submitted by the firm
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	Selected based on USP Chapter <711> and chapter <1094>
6.	Provide BMR for the three stability batches.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

630.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2258: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……50mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process

		control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.		
API Lot No.	AFPH007658		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RDM-001	RDM-002	RDM-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	06-06-2022	06-06-2022	06-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

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Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
6.	Provide BMR for the three stability batches.	

Decision of 330th meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	Crystalline Form A
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	Submitted by the firm
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	For the performance of CDP studies two standard solutions are prepared by same media and established dissolution method submitted is with same media which show release more than 85% in 30 mins. Updated CDP report which is calculated against established method standard solution show result less than release.
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies	Submitted by the firm

	were conducted.	
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	Selected based on USP Chapter <711> and chapter <1094>
6.	Provide BMR for the three stability batches.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

631.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2259: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……100mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
API Lot No.	AFPH007658
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	RDH-001	RDH-002	RDH-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	08-06-2022	08-06-2022	08-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	The pharmaceutical equivalence studies have been performed for 50mg strength of applied product. Clarification is required in this regard.	
4.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	
5.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies	

	were conducted.	
6.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
7.	Provide BMR for the three stability batches.	

Decision of 330th meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	Crystalline Form A
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	Submitted by the firm
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	For the performance of CDP studies two standard solutions are prepared by same media and established dissolution method submitted is with same media which show release more than 85% in 30 mins. Updated CDP report which is calculated against established method standard solution show result less than release.
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	Submitted by the firm
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	Selected based on USP Chapter <711> and chapter <1094>
6.	Provide BMR for the three stability batches.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

632.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 857: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 125mg/5ml 60ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate…125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-18	TR-CEP-19	TR-CEP-20
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	29-07-2021	29-07-2021	29-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
5.	Submit COA of relevant batch of drug substance used in product development and	

	stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
6.	Specify whether the drug substance used is compacted or micronized	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence and CDP studies.	
	Submit preservative effectiveness studies	
10	Submit microbial attributes of the drug product	
10.	Submit compatibility studies in section 3.2.P.2.6	
11.	Justify why your analytical procedure is different from USP monograph.	
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
13	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	Firm has submitted reference of Duricef 125mg/5ml suspension from USFDA. The product is discontinued, however the drugs@FDA database specifies that **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons** However the FDA approved product contains cefadroxil hemihydrate instead of cefadroxil monohydrate.
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml Reconstituted Suspension Contains: Cefadroxil as Monohydrate…125mg
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted
5.	Submit COA of relevant batch of drug substance used in product development and stability studies from both	Firm has submitted COA of Batch No 002230/050/2020 from drug substance

	drug substance as well as drug product manufacturer in section 3.2.S.4.4.	manufacturer and drug product manufacturer.
6.	Specify whether the drug substance used is compacted or micronized	Cefadroxil micronized
7.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
9.	Submit report of pharmaceutical equivalence and CDP studies.	Firm has submitted pharmaceutical equivalence and CDP studies against Duricef suspension.
	Submit preservative effectiveness studies	Submitted.
10	Submit microbial attributes of the drug product	Submitted.
10.	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug-excipient compatibility studies **instead** of compatibility studies with the diluent in section 3.2.P.2.6
11.	Justify why your analytical procedure is different from USP monograph.	Firm has submitted their method and claimed it to be exactly as per USP however the column used by firm is 25cm x 4.6mm x 5um while USP recommends 25cm x 4mm.
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
13	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

633.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section.

		• Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 857: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 250mg/5ml 60ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate…250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-21	TR-CEP-22	TR-CEP-23
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	29-07-2021	29-07-2021	29-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from	

	both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is compacted or micronized	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Justify why your analytical procedure is different from USP monograph.	
11.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
12	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml Reconstituted Suspension Contains: Cefadroxil as Monohydrate…250mg
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted COA of Batch No 002230/050/2020 from drug substance manufacturer and drug product manufacturer.
5.	Specify whether the drug substance used is compacted or micronized	Cefadroxil micronized
6.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
8.	Submit report of pharmaceutical equivalence and CDP studies.	Firm has submitted pharmaceutical equivalence and CDP studies against Duricef suspension.
9.	Submit preservative effectiveness studies	Submitted.
	Submit microbial attributes of the drug product	Submitted.

10	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug-excipient compatibility studies **instead** of compatibility studies with the diluent in section 3.2.P.2.6
10.	Justify why your analytical procedure is different from USP monograph.	Firm has submitted their method and claimed it to be exactly as per USP however the column used by firm is 25cm x 4.6mm x 5um while USP recommends 25cm x 4mm.
11.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
12	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

634.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 849: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefadroxil …500mg

	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	
Description of Pack (Container closure system)	Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	~~TR-CEP-21~~	~~TR-CEP-22~~	~~TR-CEP-23~~
Batch Size	~~1000 bottles~~	~~1000 bottles~~	~~1000 bottles~~
Manufacturing Date	~~07-2021~~	~~07-2021~~	~~07-2021~~
Date of Initiation	~~29-07-2021~~	~~29-07-2021~~	~~29-07-2021~~
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is compacted or micronized	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit data in section 3.2.P.8.1 as per the CTD guidance document	
	Submit stability data sheet of three stability batches	
10	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance	

	document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
10.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each Capsule Contains: Cefadroxil as Monohydrate…500mg
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted copy of COA of batch number 002240/012/2021 from API manufacturer and product manufacturer.
5.	Specify whether the drug substance used is compacted or micronized	Compacted.
6.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
8.	Submit report of pharmaceutical equivalence and CDP studies.	Firm has submitted report of pharmaceutical equivalence and CDP studies against Duricef Capsule.
9.	Submit data in section 3.2.P.8.1 as per the CTD guidance document	Submitted
	Submit stability data sheet of three stability batches	<table><tr><td>Batch No</td><td>TR-CEF-01</td><td>TR-CEF-02</td><td>TR-CEF-03</td></tr><tr><td>Batch Size</td><td>1150 capsule</td><td>1150 capsule</td><td>1150 capsule</td></tr><tr><td>Mfg Date</td><td>06-2021</td><td>06-2021</td><td>06-2021</td></tr><tr><td>Initiation date</td><td>03-07-2021</td><td>03-07-2021</td><td>03-07-2021</td></tr></table>
10	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
10.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

635.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5097: 22-02-2023
	Details of fee submitted	PKR 30,000/-: 10-01-2022
	The proposed proprietary name / brand name	**CURAGON 125mg/5ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephalexin……125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ceporex suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-30	TR-CEP-31	TR-CEP-32
Batch Size	900 bottles	900 bottles	900 bottles
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Justify the use of compacted API to manufacture suspension	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml after reconstitution contains: Cefalexin as Monohydrate…125mg
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.

3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted COA of Batch # 00213/007/2021 from API manufacturer as well as product manufacturer.
5.	Justify the use of compacted API to manufacture suspension	We hereby confirm that the drug substance used is "Cephalexin Micronized"
6.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
8.	Submit report of pharmaceutical equivalence and CDP studies.	Firm has submitted report of pharmaceutical equivalence and CDP studies against Ceporex Suspension of GSK
9.	Submit preservative effectiveness studies	Submitted
	Submit microbial attributes of the drug product	Submitted
10	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug excipient compatibility studies **instead** of compatibility with recommended diluent.
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

636.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section.

		• Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4883: 20-02-2023
	Details of fee submitted	PKR 30,000/-: 10-01-2022
	The proposed proprietary name / brand name	**CURAGON 250mg/5ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephalexin……250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ceporex suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	

	Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-33	TR-CEP-34	TR-CEP-35
Batch Size	900 bottles	900 bottles	900 bottles
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	

5.	Justify the use of compacted API to manufacture suspension	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:

Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml after reconstitution contains: Cefalexin as Monohydrate…250mg
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted COA of Batch # 00213/007/2021 from API manufacturer as well as product manufacturer.
5.	Justify the use of compacted API to manufacture suspension	We hereby confirm that the drug substance used is "Cephalexin Micronized"
6.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
8.	Submit report of pharmaceutical equivalence and CDP studies.	Firm has submitted report of pharmaceutical equivalence and CDP studies against Ceporex Suspension of GSK
9.	Submit preservative effectiveness studies	Submitted
	Submit microbial attributes of the drug product	Submitted
10	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug excipient compatibility studies **instead** of compatibility with recommended diluent.

10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

637.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 850: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephradine…125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Velosef 125mg suspension by GSK

	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-15	TR-CEP-16	TR-CEP-17
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	26-07-2021	26-07-2021	26-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
3.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
4.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
5.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
6.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
7.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
8.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	
9.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
10	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
10.	Submit report of pharmaceutical equivalence studies.	
11.	Submit compatibility studies in section 3.2.P.2.6	
12	Justify why your analytical procedure is different from USP monograph.	

13	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
14	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	Firm has submitted that Cephradine 125mg/5ml Suspension is registered / Approved in USFDA Orange Book Edition 44. However, this product is listed under **Discontinued Drug Product List**.
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml of reconstituted suspension contains: Cephradine as Monohydrate…….125mg
3.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	Our API manufacturer is testing the drug substance using both USP and BP. Firm has again submitted its specifications.
4.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
5.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
6.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted copy of COA of Batch # 00203/081/2021 from both API manufacturer as well as product manufacturer.
7.	Specify whether the drug substance used is cephradine or cephradine monohydrate	Cephradine monohydrate
8.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	We have used cephradine micronized.
9.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	Submitted.
10	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	Seprate stability data of both substances is submitted by the firm.
10.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
11.	Submit report of pharmaceutical equivalence studies.	Firm has submitted pharmaceutical equivalence along with Velosef suspension.
12	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug-excipient compatibility studies instead of compatibility studies with recommended diluent.

13	Justify why your analytical procedure is different from USP monograph.	We are testing as per USP.
14	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
15	Submit BMR of three stability batches.	Submitted.

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

i. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
ii. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
iii. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
iv. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

638.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4882: 20-02-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephradine…250mg

	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef 250mg suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00203/163/2020
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-12	TR-CEP-13	TR-CEP-14
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	26-07-2021	26-07-2021	26-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
5.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
6.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
7.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	
8.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
9.	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	

	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
10	Submit report of pharmaceutical equivalence studies.	
10.	Submit compatibility studies in section 3.2.P.2.6	
11.	Justify why your analytical procedure is different from USP monograph.	
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
13	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each 5ml of reconstituted suspension contains: Cephradine as Monohydrate…….250mg
2.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	Our API manufacturer is testing the drug substance using both USP and BP. Firm has again submitted its specifications.
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
5.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted copy of COA of Batch # 00203/081/2021 from both API manufacturer as well as product manufacturer.
6.	Specify whether the drug substance used is cephradine or cephradine monohydrate	Cephradine monohydrate
7.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	We have used cephradine micronized.
8.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	Submitted.
9.	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	Seprate stability data of both substances is submitted by the firm.
	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
10	Submit report of pharmaceutical equivalence studies.	Firm has submitted pharmaceutical equivalence along with Velosef suspension.

10.	Submit compatibility studies in section 3.2.P.2.6	Firm has submitted drug-excipient compatibility studies instead of compatibility studies with recommended diluent.
11.	Justify why your analytical procedure is different from USP monograph.	We are testing as per USP.
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
13	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

639.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2552: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cephradine…250mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cephradine capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-01	TR-CEP-02	TR-CEP-03

Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	02-07-2021	02-07-2021	02-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	

10	Justify why your analytical procedure is different from USP monograph.	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each capsule contains: Cephradine as Monohydrate…….250mg
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	Our API manufacturer is testing the drug substance using both USP and BP. Firm has again submitted its specifications.
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted copy of COA of Batch # 00204/081/2021 from both API manufacturer as well as product manufacturer.
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	Cephradine monohydrate
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	We have used cephradine compacted.
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	Submitted.
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	Seprate stability data of both substances is submitted by the firm.
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	Firm has submitted pharmaceutical equivalence and CDP studies along with Velosef Capsule.
10	Justify why your analytical procedure is different from USP monograph.	We are testing as per USP.
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall	Submitted by the firm. Firm has also submitted following:

	be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

640.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2553: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cephradine…500mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cephradine capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-01	TR-CEP-02	TR-CEP-03
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	02-07-2021	02-07-2021	02-07-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	
10	Justify why your analytical procedure is different from USP monograph.	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	

11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each capsule contains: Cephradine as Monohydrate…….500mg
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	Our API manufacturer is testing the drug substance using both USP and BP. Firm has again submitted its specifications.
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Submitted.
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	Firm has submitted copy of COA of Batch # 00204/081/2021 from both API manufacturer as well as product manufacturer.
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	Cephradine monohydrate
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	We have used cephradine compacted.
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	Submitted.
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	Seprate stability data of both substances is submitted by the firm.
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	Submitted.
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	Firm has submitted pharmaceutical equivalence and CDP studies along with Velosef Capsule.
10	Justify why your analytical procedure is different from USP monograph.	We are testing as per USP.
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

641.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 858: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…250mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	

15.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each vial contains: Cephradine (with L-arginine) …….250mg
2.	Submit valid GMP certificate / inspection report of the drug product manufacturer.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted.
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	Our drug substance is Cephradine (with L-arginine)
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	Submitted.
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	Firm has submitted COA of Batch # 00401/004/2021 from both API manufacturer as well as product manufacturer.
7.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	Firm has submitted copy of purchase invice from Varioline Intercool and data logger record.
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	Submitted.
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	Firm has submitted pharmaceutical equivalence studies with Velosef Injection.
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	Firm has submitted in use stability studies.
12.	Submit microbiological attributes in section 3.2.P.2.6.	Submitted.
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	Submitted.
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Submitted by the firm. Batch No: TR-CEP-04 / TR-CEP-05 / TR-CEP-06 Batch Size: 1100 Vials / 1100 Vials / 1100 Vials Mfg Date: 07-2021 / 07-2021 / 07-2021 Initiation date: 09-07-2021 / 09-07-2021 / 09-07-2021

		Firm has also submitted following: 1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019. 2. Firm has submitted copy of proforma invoice dated 30-04-2021. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
15.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

642.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2554: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…500mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-07	TR-CEP-08	TR-CEP-09
Batch Size	1100 vials	1100 vials	1100 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill	

	weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
15.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each vial contains: Cephradine (with L-arginine) …….500mg
2.	Submit valid GMP certificate / inspection report of the drug product manufacturer.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted.
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	Our drug substance is Cephradine (with L-arginine)
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	Submitted.
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	Firm has submitted COA of Batch # 00401/004/2021 from both API manufacturer as well as product manufacturer.
7.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	Firm has submitted copy of purchase invice from Varioline Intercool and data logger record.
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	Submitted.
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	Firm has submitted pharmaceutical equivalence studies with Velosef Injection.
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	Firm has submitted in use stability studies.
12.	Submit microbiological attributes in section 3.2.P.2.6.	Submitted.
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	Submitted.

<table>
<tr><td>14.</td><td>Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.</td><td>Submitted by the firm.
<table>
<tr><td>Batch No</td><td>TR-CEP-07</td><td>TR-CEP-08</td><td>TR-CEP-09</td></tr>
<tr><td>Batch Size</td><td>1100 Vials</td><td>1100 Vials</td><td>1100 Vials</td></tr>
<tr><td>Mfg Date</td><td>07-2021</td><td>07-2021</td><td>07-2021</td></tr>
<tr><td>Initiation date</td><td>09-07-2021</td><td>09-07-2021</td><td>09-07-2021</td></tr>
</table>
Firm has also submitted following:
1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019.
2. Firm has submitted copy of proforma invoice dated 30-04-2021.
3. Copy of HPLC compliance certificate
4. Record of digital data logger.</td></tr>
<tr><td>15.</td><td>Submit BMR of three stability batches.</td><td>Submitted.</td></tr>
</table>

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

643.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 851: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…1g
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
API Lot No.	
Description of Pack (Container closure system)	Glass vials
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	TR-CEP-10	TR-CEP-11	TR-CEP-12
Batch Size	1100 vials	1100 vials	1100 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	

10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
15.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Firm has submitted revised label claim along with submission of 30,000 fee for correction as under: Each vial contains: Cephradine (with L-arginine) …….1g
2.	Submit valid GMP certificate / inspection report of the drug product manufacturer.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted.
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	Our drug substance is Cephradine (with L-arginine)
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	Submitted.
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	Firm has submitted COA of Batch # 00401/004/2021 from both API manufacturer as well as product manufacturer.
7.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	Firm has submitted copy of purchase invice from Varioline Intercool and data logger record.
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	Submitted.
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	Firm has submitted pharmaceutical equivalence studies with Velosef Injection.

<table>
<tr><td>11.</td><td>Submit data of compatibility of the drug product in section 3.2.P.2.5.</td><td>Firm has submitted in use stability studies.</td></tr>
<tr><td>12.</td><td>Submit microbiological attributes in section 3.2.P.2.6.</td><td>Submitted.</td></tr>
<tr><td>13.</td><td>Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.</td><td>Submitted.</td></tr>
<tr><td>14.</td><td>Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.</td><td>Submitted by the firm.
<table>
<tr><td>Batch No</td><td>TR-CEP-10</td><td>TR-CEP-11</td><td>TR-CEP-12</td></tr>
<tr><td>Batch Size</td><td>1100 Vials</td><td>1100 Vials</td><td>1100 Vials</td></tr>
<tr><td>Mfg Date</td><td>07-2021</td><td>07-2021</td><td>07-2021</td></tr>
<tr><td>Initiation date</td><td>09-07-2021</td><td>09-07-2021</td><td>09-07-2021</td></tr>
</table>
Firm has also submitted following:
1. Copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019.
2. Firm has submitted copy of proforma invoice dated 30-04-2021.
3. Copy of HPLC compliance certificate
4. Record of digital data logger.</td></tr>
<tr><td>15.</td><td>Submit BMR of three stability batches.</td><td>Submitted.</td></tr>
</table>

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

644.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19212: 02-08-2023
	Details of fee submitted	PKR 30,000/-: 27-04-2023
	The proposed proprietary name / brand name	**CEFOSS 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Soidum …250mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cefizox Injection by Barrett Hodgson
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China		
API Lot No.	12C0302104005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-66	TR-CEP-67	TR-CEP-68
Batch Size	1719 vials	1719 vials	1719 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	17-09-2021	17-09-2021	17-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of reference standard used in the analysis of drug substance.	
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	
6.	Specify the fill weight of the product per vial.	

7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	**No response** submitted by the firm
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Analyical method verification studies performed on drug product shall be same as performed for drug substance since no excipient is used.
4.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	Submitted.
6.	Specify the fill weight of the product per vial.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	We are using ready to fill drug substance therefore compatibility studies are not required.
8.	Submit report of pharmaceutical equivalence studies.	Firm has submitted pharmaceutical equivalence against Cefizox Injection of Barret Hodgson
9.	Submit preservative effectiveness studies	Submitted
	Submit microbial attributes of the drug product	Submitted
10	Submit compatibility studies in section 3.2.P.2.6	Submitted
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Stability data is submitted. Firm has also submitted following: 1. Copy of Manufacturing License of API manufacturer issued by NMPA China valid till 26-10-2025. 2. Copy of commercial invoice cleared dated 13-08-2021 specifying 10 kg API. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

	i. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. **ii. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **iii. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **iv. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
645.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19211: 02-08-2023
	Details of fee submitted	PKR 30,000/-: 27-04-2023
	The proposed proprietary name / brand name	**CEFOSS 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Soidum …1g
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cefizox Injection by Barrett Hodgson
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China		
API Lot No.	12C0302104005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-10	TR-CEP-11	TR-CEP-12
Batch Size	1080 vials	1080 vials	1080 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of reference standard used in the analysis of drug substance.	
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	
6.	Specify the fill weight of the product per vial.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	**No response** submitted by the firm
2.	Submit specifications as well as analytical method of the drug substance from the drug	Submitted.

	product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	Analyical method verification studies performed on drug product shall be same as performed for drug substance since no excipient is used.
4.	Submit COA of reference standard used in the analysis of drug substance.	Submitted.
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	Submitted.
6.	Specify the fill weight of the product per vial.	Submitted.
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	We are using ready to fill drug substance therefore compatibility studies are not required.
8.	Submit report of pharmaceutical equivalence studies.	Firm has submitted pharmaceutical equivalence against Cefizox Injection of Barret Hodgson
9.	Submit preservative effectiveness studies	Submitted
	Submit microbial attributes of the drug product	Submitted
10	Submit compatibility studies in section 3.2.P.2.6	Submitted
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	Stability data is submitted. Firm has also submitted following: 1. Copy of Manufacturing License of API manufacturer issued by NMPA China valid till 26-10-2025. 2. Copy of commercial invoice cleared dated 13-08-2021 specifying 10 kg API. 3. Copy of HPLC compliance certificate 4. Record of digital data logger.
11.	Submit BMR of three stability batches.	

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

i. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
ii. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
iii. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
iv. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

646.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Mass Pharma dated 14-12-2020 based on the inspection dated 23-09-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section to M/s Mass Pharma dated 18-12-2017. The letter specifies Soft gelatin capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31571: 03-11-2022
	Details of fee submitted	PKR 75,000/-: 06-09-2022
	The proposed proprietary name / brand name	**MCUTANE 20mg Softgel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Retinoids
	Reference to Finished product specifications	BP
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Arynoin capsule by Mass pharma
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Maxinoin capsule by Maxitech pharma Firm has submitted result of CDP studies against the comparator i.e. Maxinoin capsule by Maxitech pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	20210117		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C237	C285	C293
Batch Size	48195 Capsule	48195 Capsule	48195 Capsule
Manufacturing Date	01-2021	03-2021	03-2021
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. CQ20180013) issued by CFDA China. The certificate is valid till 06-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 11-02-2021 specifying import of 20Kg Isotretinoin. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for stability batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	
2.	Submit data of initiation of stability studies of all batches	
3.	Provide COA of reference standard used in the stability studies.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	Submitted
2.	Submit data of initiation of stability studies of all batches	Submitted
3.	Provide COA of reference standard used in the stability studies.	The BP method used A (1%, 1cm) value and no reference standard is used due to degradable nature of isotretinoin within months.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

647.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Mass Pharma dated 14-12-2020 based on the inspection dated 23-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section to M/s Mass Pharma dated 18-12-2017. The letter specifies Soft gelatin capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17863: 20-06-2022
	Details of fee submitted	PKR 75,000/-: 25-05-2022
	The proposed proprietary name / brand name	**ACNEFON 20mg Softgel Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Retinoids
	Reference to Finished product specifications	BP
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Arynoin capsule by Mass pharma
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Maxinoin capsule by Maxitech pharma Firm has submitted result of CDP studies against the comparator i.e. Maxinoin capsule by Maxitech pharma

	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	20210117		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C237	C285	C293
Batch Size	48195 Capsule	48195 Capsule	48195 Capsule
Manufacturing Date	01-2021	03-2021	03-2021
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. CQ20180013) issued by CFDA China. The certificate is valid till 06-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 11-02-2021 specifying import of 20Kg Isotretinoin. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for stability batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	
2.	Submit data of initiation of stability studies of all batches	
3.	Provide COA of reference standard used in the stability studies.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	Submitted
2.	Submit data of initiation of stability studies of all batches	Submitted
3.	Provide COA of reference standard used in the stability studies.	The BP method used A (1%, 1cm) value and no reference standard is used due to degradable nature of isotretinoin within months.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

648.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gallop Water Sciences. Plot No. 404, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Mass Pharma dated 14-12-2020 based on the inspection dated 23-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section to M/s Mass Pharma dated 18-12-2017. The letter specifies Soft gelatin capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19952: 07-07-2022
	Details of fee submitted	PKR 75,000/-: 23-06-2022
	The proposed proprietary name / brand name	**ZITNOIN 20mg Softgel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Retinoids
	Reference to Finished product specifications	BP
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Arynoin capsule by Mass pharma

	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Maxinoin capsule by Maxitech pharma Firm has submitted result of CDP studies against the comparator i.e. Maxinoin capsule by Maxitech pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China
API Lot No.	20210117
Description of Pack (Container closure system)	Alu-alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C237	C285	C293
Batch Size	48195 Capsule	48195 Capsule	48195 Capsule
Manufacturing Date	01-2021	03-2021	03-2021
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. CQ20180013) issued by CFDA China. The certificate is valid till 06-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 11-02-2021 specifying import of 20Kg Isotretinoin. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for stability batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	
2.	Submit data of initiation of stability studies of all batches	
3.	Provide COA of reference standard used in the stability studies.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	Submitted
2.	Submit data of initiation of stability studies of all batches	Submitted
3.	Provide COA of reference standard used in the stability studies.	The BP method used A (1%, 1cm) value and no reference standard is used due to degradable nature of isotretinoin within months.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
649.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Mass Pharma dated 14-12-2020 based on the inspection dated 23-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section to M/s Mass Pharma dated 18-12-2017. The letter specifies Soft gelatin capsule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21516: 29-07-2022
	Details of fee submitted	PKR 75,000/-: 23-06-2022
	The proposed proprietary name / brand name	**ISONOIN 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Retinoids
	Reference to Finished product specifications	BP
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Arynoin capsule by Mass pharma
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Maxinoin capsule by Maxitech pharma Firm has submitted result of CDP studies against the comparator i.e. Maxinoin capsule by Maxitech pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	20210117		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C237	C285	C293
Batch Size	48195 Capsule	48195 Capsule	48195 Capsule
Manufacturing Date	01-2021	03-2021	03-2021
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. CQ20180013) issued by CFDA China. The certificate is valid till 06-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 11-02-2021 specifying import of 20Kg Isotretinoin. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for stability batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	
2.	Submit data of initiation of stability studies of all batches	
3.	Provide COA of reference standard used in the stability studies.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability studies data as per zone IV-A conditions.	Submitted
2.	Submit data of initiation of stability studies of all batches	Submitted
3.	Provide COA of reference standard used in the stability studies.	The BP method used A (1%, 1cm) value and no reference standard is used due to degradable nature of isotretinoin within months.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

650.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-09-2021 based on evaluation conducted on 06-08-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 14-09-2021 specifying Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22884 dated 12-08-2022
	Details of fee submitted	PKR 75,000/- Dated 19-04-2022
	The proposed proprietary name / brand name	**XYSARTAN 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 40mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	Yellow colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	10's, 20's, 30's, 28's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi 40mg Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 40mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	21AK000004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-091/T1/S1	RD/PR21-091/T1/S2	RD/PR21-091/T1/S2
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	

Decision of 335th meeting of Registration Bord:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug	Submitted

	substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	Upon Query to API manufacturer, it was informed that stability studies was performed on 5°C± 3°C & 25°C ± 2°C, 60% RH ± 5% accordingly the storage condition is 2-8°C. However, there was an error in stability reports. Firm has now submitted new stability data conducted at 5°C± 3°C & 25°C ± 2°C, 60% RH ± 5%
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	Formulation contain mannitol which is solublizer for poorly water soluble compounds, mannitol is the substance giving enhancing release profile. Moreover same released profile is observed with innovator product i.e. Edarbi. Mannitol is also used by the Innovator's product in its formulation.
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	Firm has now submitted testing method which contains 45 minutes time point for dissolution.
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	Standard solution concentration is 0.06mg/ml while the correct limit of quantitation is 0.00658mg/ml. However there was small error in AMV Report.
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	Firm has submittedcopy of commercial invoice cleared dated 28-06-2021. However the invoice is not readable to identify the batch number of API and other details.
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat state India valid till 29-05-2025.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

651.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-09-2021 based on evaluation conducted on 06-08-2021

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 14-09-2021 specifying Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22883 dated 12-08-2022
	Details of fee submitted	PKR 75,000/- Dated 19-04-2022
	The proposed proprietary name / brand name	**XYSARTAN 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 80mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	Yellow colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	10's, 20's, 30's, 28's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi 80mg Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 80mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	21AK000004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-084/T1/S1	RD/PR21-084/T1/S2	RD/PR21-084/T1/S2
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	

Decision of 335th meeting of Registration Bord:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	Upon Query to API manufacturer, it was informed that stability studies was performed on 5°C± 3°C & 25°C ± 2°C, 60% RH ± 5% accordingly the storage condition is 2-8°C. However, there was an error in stability reports. Firm has now submitted new stability

		data conducted at 5°C± 3°C & 25°C ± 2°C, 60% RH ± 5%
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	Formulation contain mannitol which is solublizer for poorly water soluble compounds, mannitol is the substance giving enhancing release profile. Moreover same released profile is observed with innovator product i.e. Edarbi. Mannitol is also used by the Innovator's product in its formulation.
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	Firm has now submitted testing method which contains 45 minutes time point for dissolution.
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	Standard solution concentration is 0.06mg/ml while the correct limit of quantitation is 0.00658mg/ml. However there was small error in AMV Report.
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	Firm has submittedcopy of commercial invoice cleared dated 28-06-2021. However the invoice is not readable to identify the batch number of API and other details.
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat state India valid till 29-05-2025.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

652.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A, Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 11th November 2021 for following sections:

		1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. AWD-AZD-ADV4: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 20-12-2023
	The proposed proprietary name / brand name	**FLIMOXIN 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Levofloxacin as hemihydrate…….250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Leflox Tablet by Getz
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Leflox Tablet of Getz. Firm has submitted CDP studies in 3 medium against Leflox Tablet of Getz
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China		
API Lot No.	DC-004-2205017		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 25-10-2022 specifying 300Kg levofloxacin dated by legacy pharma.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	
3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	Submitted
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	Submitted
3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

653.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A, Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: 4PL-PG2-VU36: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 21-12-2023
	The proposed proprietary name / brand name	**FLIMOXIN 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Levofloxacin as hemihydrate…….500 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Leflox Tablet by Getz
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against

		Leflox Tablet of Getz. Firm has submitted CDP studies in 3 medium against Leflox Tablet of Getz
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China		
API Lot No.	DC-004-2205017		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 25-10-2022 specifying 300Kg levofloxacin dated by legacy pharma.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	

3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	Submitted
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	Submitted
3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

654.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23835 dated 23-08-2022
	Details of fee submitted	PKR 30,000/- Dated 25-07-2022
	The proposed proprietary name / brand name	**PENTAL 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl…….75mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	Innovator's

	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nucynta TAblet (**USFDA** Approved)
	For generic drugs (me-too status)	Tapento Tablet by Sami
	Name and address of API manufacturer.	Arene Life Sciences Private Limited (Unit-1) Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy Dist, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Tapento IR Tablet of Sami Firm has submitted results of CDP studies for their product against Tapento IR Tablet of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Arene Life Sciences Private Limited (Unit-1) Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy Dist, Telangana, India.
API Lot No.	TPD01190001/U-1
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	29-11-2021	29-11-2021	29-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA Government of Telanganaa India issued on 09-10-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted
2.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	Not submitted
3.	Submit stability study data of API as per zone IV-A conditions.	The submitted stability data is as per zone II instead of zone IV-A
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted
5.	Submit documents confirming import of API	Not submitted
6.	Submit stability studies as per 6 points checklist specified in the CTD guidance document.	Not submitted

Decision of 335th meeting of Registration Board:

Deferred for following submissions:

- Verification studies of analytical method of drug substance performed by drug product manufacturer.
- Stability study data of API as per zone IV-A conditions.
- Documents for the procurement of API with approval from DRAP (in case of import).

- Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Verification studies of analytical method of drug substance performed by drug product manufacturer.	Submitted
2.	Stability study data of API as per zone IV-A conditions.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	AD cleared invoice is submitted.
4.	Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

655.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 25814 dated 13-09-2022
	Details of fee submitted	PKR 30,000/- Dated 12-09-2022
	The proposed proprietary name / brand name	**AFTANIL 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rebamipide…100mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Anti ulcer
	Reference to Finished product specifications	JP
	Proposed Pack size	100’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mucosta Tablet (**PMDA** Japan Approved)

	For generic drugs (me-too status)	Mucosta Tablet by Otsuka
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Mucosta Tablet of Otsuka Firm has submitted results of CDP studies for their product against Mucosta Tablet of Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
API Lot No.	05-20210624C
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	01-04-2022	01-04-2022	01-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Translated Copy of DML certificate issued by CFDA China valid till 26-11-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of me-too status since fee of generic application is submitted.	Mucosta Tablet by Otsuka
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has only submitted specifications and analytical method of drug substance from product manufacturer, however the specifications of drug substance manufacturer are not submitted.
3.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Not submitted
4.	Submit documents confirming import of API	Not submitted
5.	Submit stability studies as per 6 points checklist specified in the CTD guidance document.	Not submitted

Decision of 335th meeting of Registration Board:

Deferred for following submissions:

- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.
- Details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted.
- Documents for the procurement of API with approval from DRAP (in case of import).

- Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.	Submitted
2.	Details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

656.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 13-01-2022 specifying sachet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: LLE-ZZV-UWH1 dated 14-12-2023
	Details of fee submitted	PKR 30,000/- Dated 21-11-2023
	The proposed proprietary name / brand name	**KOLSET Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Cholestyramine.....4g
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Other Antilipemics / Lipid-regulating drug

	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Questran 4g/sachet Powder for Oral Suspension (MHRA Approved)
	For generic drugs (me-too status)	Could not be confirmed
	Name and address of API manufacturer.	Phaex Polymers Private Limited Plot F10, MIDC Murbod Thane 421401 Maharasthra India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Questran 4g sachet
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Phaex Polymers Private Limited Plot F10, MIDC Murbod Thane 421401 Maharasthra India
API Lot No.	
Description of Pack (Container closure system)	Aluminium sachet

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	069NS01	069NS02	069NS03
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	24-04-2023	24-04-2023	24-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by FDA Mahrashtra India valid till 03-03-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import issued dated 31-05-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of me-too status, since you hve selected the product status as generic product and also submitted 30,000 fee as a generic product.	
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
3.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	
4.	Specify why module 3.2.S and DMF are separately submitted as different documents	
5.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical studies are conducted	
6.	Justify why in vitro binding and dissolution studies are not conducted under the product development, since both these studies are recommended in the public assessment reports	
7.	Submit clearance certificate as evidence of import of API	

Decision of 333rd meeting of Registration Board:
Deferred for submission of reply to the above cited shortcoming.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of me-too status, since you hve selected the product status as generic product and also submitted 30,000 fee as a generic product.	Firm has submitted 45,000 differential fee.
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Suubmitted
3.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	Submitted
4.	Specify why module 3.2.S and DMF are separately submitted as different documents	No response submitted
5.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical studies are conducted	Submitted.
6.	Justify why in vitro binding and dissolution studies are not conducted under the product development, since both these studies are recommended in the public assessment reports	The product specifications adopted for Cholestyramine 4g Sachet are USP. Dissolution test is not included in USP monograph of "Cholestyramine for oral suspension". Pharmaceutical equivalence is performed between test product (Cholestyramine 4g Sachet) and reference product (Questran 4g Sachet), both the test and reference product are tested for description, identification, average weight, assay, microbiological enumeration test and test for specified microorganism according to USP monograph. Both the products comply with the specifications of USP for all the above mentioned tests. The formulation of test and reference product is same in this way both the test and reference products are interchangeable. Alternative to in vitro binding studies, USP Assay method is also based upon exchange capacity of Cholestyramine resin against sodium glycocholate, in this method cholestyramine resin acts as adsorbent and sodium glycocholate as adsorbate. In this way we are testing binding of bile salt with cholestyramine during test of assay and all the results are within specified limits of USP
7.	Submit clearance certificate as evidence of import of API	AD cleared invoice / clearance certificate is not submitted

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

657.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Saffron Pharma dated 12-11-2020 based on the inspection dated 11-11-2020.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6371: 06-03-2023
	Details of fee submitted	PKR 75,000/-: 11-01-2023
	The proposed proprietary name / brand name	**MITOS 50mcg Nasal Spray**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Spray Contains: Mometasone Furoate…50mcg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Decongestant and other nasal preparations for topical use.
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not submitted
	For generic drugs (me-too status)	Nasomet Aqueous Nasal Spray by Sante
	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Nasal spray section (steroid) Regularization.
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	Submitted
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	MHRA approved

4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	Correct label claim submitted
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	Submitted

Decsion: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

658.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma Pvt Ltd. 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Saffron Pharma dated 12-11-2020 based on the inspection dated 11-11-2020.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10718: 28-04-2022
	Details of fee submitted	PKR 75,000/-: 15-03-2022
	The proposed proprietary name / brand name	**METASONE Nasal Spray 50mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Spray Contains: Mometasone Furoate…50mcg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Decongestant and other nasal preparations for topical use.
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not submitted
	For generic drugs (me-too status)	Nasomet Aqueous Nasal Spray by Sante

	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
API Lot No.	
Description of Pack (Container closure system)	
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Nasal spray section (steroid) Regularization.
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	Submitted
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	MHRA approved
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	Correct label claim submitted
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	Submitted

Decsion: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

573.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Saffron Pharma dated 12-11-2020 based on the inspection dated 11-11-2020.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 470: 05-01-2023
	Details of fee submitted	PKR 75,000/-: 21-12-2022
	The proposed proprietary name / brand name	**Metason 50mcg Nasal Spray**
	Strength / concentration of drug of Active	Each Spray Contains:

	Pharmaceutical ingredient (API) per unit	Mometasone Furoate…50mcg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Decongestant and other nasal preparations for topical use.
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not submitted
	For generic drugs (me-too status)	Nasomet Aqueous Nasal Spray by Sante
	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. “Each Spray Contains:	

	Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	Firm has submitted copy of letter of renewal of DML dated 16-05-2024 specifying Nasal spray section (steroid) Regularization.
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	Submitted
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	MHRA approved
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	Correct label claim submitted
5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.	Submitted

Decsion: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

659.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Arsons Pharmaceutical Industries (Pvt.) Ltd. 2.5 Km Defense Road, off Multan Road, Lahore Pakistan**
	Name, address of Manufacturing site.	Arsons Pharmaceutical Industries (Pvt.) Ltd. 2.5 Km Defense Road, off Multan Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 18-09-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section of Drug Manufacturing License

		(DML No. 000514) dated 13-06-2011. The letter specifies following section: 1. Tablet (General) 2. Capsule (General antibiotic)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24060: 01-09-2021
	Details of fee submitted	PKR 30,000/- : 30-06-2021
	The proposed proprietary name / brand name	**ROMEPRAZOLE -40 Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Omeprazole (as enteric coated pellets)…..40mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Risek Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Omega capsule of Feroesons Lab. Firm has submitted results of CDP for their product against the comparator product Omega capsule of Feroesons Lab.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	OMP873		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RM-001	RM-002	RM-003
Batch Size	1843 Capsule	1843 Capsule	1843 Capsule
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	01-04-2020	01-04-2020	01-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify how manufacturing of omeprazole capsule is applied under section approved for general antibiotics	We are manufacturing general drugs in this section only
2.	Your submitted label claim does not specify the pellets, revise your label claim as per follow along with submission of full fee of registration: Each Capsule Contains: Omeprazole (as enteric coated pellets)…40mg	Firm has revised label claim without submission of fee
3.	Submit specifications and analytical procedures of the drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 since you have only submitted a copy of USP monograph.	Not submitted
4.	The submitted verification studies of the drug substance from drug product manufacturer does not specify the exact concentration of solution used in system suitability, and precision studies. Moreover, the concentrations specified in linearity studies are different from the concentration of standard solution specified in USP monograph. Clarification is required in this regard.	Not submitted
5.	Justify the fill weight of 179.05mg pellets per capsule.	Submitted
6.	Specify the total weight of the capsule including the weight of hard gelatin capsule.	Submitted
7.	Submit pharmaceutical equivalence of your product against the innovator / reference product.	Firm has submitted PE studies against Risek capsule by Getz Pharma
8.	Justify your CDP studies in which you have studied only 45 mins time point at 6.8pH phosphate buffer. Perform complete CDP studies as per the applicable international guidelines and analytical method as specified in USP and submit summarized complete results.	Not submitted
9.	Submit process validation protocols	Submitted
10.	Specify the exact dissolution test for your drug product specifications, since USP has mentioned two different tests for dissolutionin which acceptance criteria as well as analytical methods are different.	Dissolution test-2
11.	Submit detailed analytical method of the drug product which is available and implemented in your QC department instead of submitting copy of USP monograph.	Submitted
12.	The submitted verification studies of the drug product do not specify the exact concentration of solution used in system suitability, and precision studies. Moreover, the concentrations specified in linearity studies are different from	Submitted

	the concentration of standard solution specified in USP monograph. Clarification is required in this regard.	
13.	Provide the result of stability studies as per the format specified in the CTD guidance document since your stability data summary sheets does not provide various information i.e. mfg date, exp date, container closure system, stability initiation date, API lot number used in manufacturing of batches etc.	Not submitted
14.	Provide detailed description of your product including color and size of the capsule shell as well as color of pellets in case the shells are transparent.	Submitted
15.	Submit stability study data in section 3.2.P.8.3 as per the 6 points checklist provided in the CTD guidance document: The checklist includes following points: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Decision of 331st meeting of Registration Board:

Deferred for following submissions:

- Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Specifications and analytical procedures of the drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.
- Clarification for verification studies of the drug substance from drug product manufacturer which does not specify the exact concentration of solution used in system suitability, and precision studies. Moreover, the concentrations specified in linearity studies are different from the concentration of standard solution specified in USP monograph.
- Result of stability studies as per the format specified in the CTD guidance document since submitted stability data summary sheets does not provide information including mfg date, exp date, container closure system, stability initiation date, API lot number used in manufacturing of batches etc.
- Stability study data in section 3.2.P.8.3 as per the 6 points checklist provided in the CTD guidance document.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Rs. 30,000/- for correction/pre-approval change in product label claim is not submitted. However firm has again submitted copy of fee challan submitted along with initial application.
2.	Specifications and analytical procedures of the drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
3.	Clarification for verification studies of the drug substance from drug product manufacturer which does not specify the exact concentration of solution used in system suitability, and precision studies. Moreover, the concentrations specified in linearity studies are different from the concentration of standard solution specified in USP monograph.	Submitted
4.	Result of stability studies as per the format specified in the CTD guidance document since submitted stability data summary sheets does not provide information including mfg date, exp date, container closure system, stability initiation date, API lot number used in manufacturing of batches etc.	Submitted
5.	Stability study data in section 3.2.P.8.3 as per the 6 points checklist provided in the CTD guidance document.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

660.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, K.I.A., Karachi**
	Name, address of Manufacturing site.	M/s Liven Pharmaceuticals (Pvt) Ltd, 49-Km, Lahore Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted contract manufacturing agreement dated 29-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 31-07-2019 based on the inspection dated 03-07-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000881) dated 11-04-2018 specifying Liquid Injection Ampoule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25802: 16-09-2021
	Details of fee submitted	PKR 50,000/-: 08-05-2021 + PKR 25,000/-: 07-06-2021
	The proposed proprietary name / brand name	**ONDASET 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ondansetron (as HCl)……4mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**MHRA** Approved)
	For generic drugs (me-too status)	Onseron Injection by Indus Pharma
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.		
API Lot No.	180S002		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ON1	ON2	ON3
Batch Size	25000 Ampoules	25000 Ampoules	25000 Ampoules
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	08-06-2019	10-06-2019	13-06-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 18101065) issued by Food and Drugs Control Administration Gujrat Estate India. The certificate is valid till 18-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 3Kg Ondansetron hydrochloride cleared dated 16-04-2019. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed stability studies using UV method.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.
- Provide stability studies of three batches of drug substance as per zone IV-A conditions.

• Your qualitative composition is different from that of the innovator product. Justification is required in this regard. • Innovator product has used ondansetron hydrochloride dehydrate while you are using ondansetron hydrochloride. Justification is required in this regard. • Provide details incuding batch number, exppiry date and manufacturer of the product against which pharmaceutical equivalence studies are conducted, since Zofran 4mg/2ml injection is not registered in Pakistan. • Justify the UV method as alternate method in the analytical procedure for assay test of your product, since no such test is specified in USP monograph. • Justify the analytical method validation studies performed on UV method while USP as well as your analytical procedure specifies HPLC test. • Justify the performance of assay method using UV method which is contrary to the USP method for your commercial batches. • Provide reference of previous approval of applications with stability study data of the firm (if any) / previous product specific inspection. • Submit Batch Manufacturing Record of three stability batches.
Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.
Response by the firm: Firm has submitted a request to change the contract manufacturer from Liven Pharma to AGP Limited Karachi. Firm has submitted following dcuments: • 75,000 fee for change of contract manufacturer • Module I, Module II and Module III including data from the new contract manufacturer.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

661.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, K.I.A., Karachi**
	Name, address of Manufacturing site.	M/s Liven Pharmaceuticals (Pvt) Ltd, 49-Km, Lahore Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted contract manufacturing agreement dated 29-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 31-07-2019 based on the inspection dated 03-07-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000881) dated 11-04-2018 specifying Liquid Injection Ampoule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25803: 16-09-2021
	Details of fee submitted	PKR 50,000/-: 08-05-2021 +

		PKR 25,000/-: 07-06-2021
	The proposed proprietary name / brand name	**ONDASET 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ondansetron (as HCl)……8mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**MHRA** Approved)
	For generic drugs (me-too status)	Onseron Injection by Indus Pharma
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.		
API Lot No.	180S002		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OT1	OT2	OT3
Batch Size	25000 Ampoules	25000 Ampoules	25000 Ampoules
Manufacturing Date	04-2019	05-2019	06-2019
Date of Initiation	31-05-2019	15-06-2019	27-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 18101065) issued by Food and Drugs Control Administration Gujrat Estate India. The certificate is valid till 18-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 3Kg Ondansetron hydrochloride cleared dated 16-04-2019. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed stability studies using UV method.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.
- Provide stability studies of three batches of drug substance as per zone IV-A conditions.
- Your qualitative composition is different from that of the innovator product. Justification is required in this regard.
- Innovator product has used ondansetron hydrochloride dehydrate while you are using ondansetron hydrochloride. Justification is required in this regard.
- Provide details incuding batch number, exppiry date and manufacturer of the product against which pharmaceutical equivalence studies are conducted, since Zofran 4mg/2ml injection is not registered in Pakistan.

• Justify the UV method as alternate method in the analytical procedure for assay test of your product, since no such test is specified in USP monograph. • Justify the analytical method validation studies performed on UV method while USP as well as your analytical procedure specifies HPLC test. • Justify the performance of assay method using UV method which is contrary to the USP method for your commercial batches. • Provide reference of previous approval of applications with stability study data of the firm (if any) / previous product specific inspection. • Submit Batch Manufacturing Record of three stability batches. • Batch OT3 is manufactured on 06-2019 and placed on stability studies on 27-08-2019. Justification is required in this regard.
Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.
Response by the firm: Firm has submitted a request to change the contract manufacturer from Liven Pharma to AGP Limited Karachi. Firm has submitted following dcuments: • 75,000 fee for change of contract manufacturer • Module 1 along with cross reference to approval of same formulation of the contract manufacturer i.e. Ms AGP Limited Karachi in 326th meeting of Registration Board (Zofran 8mg/4ml Injection)
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

662.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7-km Pasrur Road Sialkot.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-06-2019.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 9702: 29-03-2021
	Details of fee submitted	PKR 50,000/-: 03-02-2021
	The proposed proprietary name / brand name	**CELAM 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan dry suspension.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF10035		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	D-006	D-018	D-022
Batch Size	80 Kg	10125 packs	5000 bottles
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	31-01-2019	31-01-2019	31-01-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Firm was communicated following shortcomings on 22nd October 2021.

- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 0.685gm of drug substance is equivalent to 100mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 7500 and as high as 60,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for batch D-220, D-221 and D-222 in section 3.2.P.5.4 while provided stability study data for batch D-006, D-018 and D-022 in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)

- Documents for the procurement of API with approval from DRAP (in case of import).
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing

- Justify why BMR of different batches is submitted than that for which stability studies were conducted.

The firm vide its reply dated 08-11-2021 have submitted stability study data of new batches. The response of the firm is as below:

We are submitting herewith the new batches stability data because from these batches we have streamlined the batch sizes. Therefore, kindly consider this stability data with all its supporting documents and disregard the previous submission. We are submitting process validation protocols and report of the same batches used in the stability studies. Please disregard the previous submission and consider this one as valid.

Firm has submitted data of new batches without justifying the queries raised in the letter of shortcomings and submitted data of new batches without fulfilling the requirements of Form 5F as per the guidelines approved by Registration Board.

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of complete data of drug substance as well as drug product in module-2 and module-3 as per the Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.
- Submission of fee of Rs. 30,000 for revision in stability data, as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.

Response by the firm:

The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
Brand Name	VARICEF 100mg/5ml Dry Suspension

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

663.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7-km Pasrur Road Sialkot.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-06-2019.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection

		dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9701: 29-03-2021
	Details of fee submitted	PKR 50,000/-: 03-02-2021
	The proposed proprietary name / brand name	**CELAM 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF10035		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	553	589	597
Batch Size	7500 packs	10000 packs	10000 packs
Manufacturing Date	05-2018	08-2018	09-2018
Date of Initiation	10-05-2018	31-08-2018	28-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:
Firm was communicated following shortcomings on 22nd October 2021.

- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.

- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.
- Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.

The firm vide its reply dated 08-11-2021 have submitted stability study data of new batches. The response of the firm is as below:
We are submitting herewith the new batches stability data because from these batches we have streamlined the batch sizes. Therefore, kindly consider this stability data with all its supporting documents and disregard the previous submission. We are submitting process validation protocols and report of the same batches used in the stability studies. Please disregard the previous submission and consider this one as valid.
Firm has submitted data of new batches without justifying the queries raised in the letter of shortcomings and submitted data of new batches without fulfilling the requirements of Form 5F as per the guidelines approved by Registration Board.

Decision of 316th meeting of Registration Board:
Deferred for following:

- Submission of complete data of drug substance as well as drug product in module-2 and module-3 as per the Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.
- Submission of fee of Rs. 30,000 for revision in stability data, as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.

Response by the firm:
The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
Brand Name	VARICEF 200mg/5ml Dry Suspension

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

c. Deferred cases of Import

664.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories B-246, Block 6,P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No.: 0002** **Address:** 246-B, Block-6, PECHS, Karachi **Validity:** 15-08-2022 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do,Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do,Republic of Korea
	Name of exporting country	South Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020-D1-3552) dated 23-10- 2020 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection. The CoPPconfirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **The name of importing country on CoPP is mentioned as Pakistan.** **GMP:** Firm has submitted legalized **GMP** certificate(No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7,Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
	Details of letter of authorization / sole agency agreement	Firm has submitted Legalized NOC from M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea which authorises **M/s Gene-TechLaboratories B-246, Block 6, P.E.C.H.S, Karachi,Pakistan** to register their products in Pakistan. The authorization letter is valid till 09-11-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for exportpurpose only

	Dy. No. and date of submission	Dy. No 10553 dated 06-04-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021
	The proposed proprietary name / brand name	**Hyal Forte Pre Filled Syringe**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe (2ml) Contains 20mg of Sodium Hyaluronate
	Pharmaceutical form of applied drug	Pre-filled syringe
	Pharmacotherapeutic Group of (API)	Hyaluronic acid
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	1's;AS per SRO
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	Hyalgan PFS 20mg/2ml approved by ANSM of France
	For generic drugs (me-too status)	Hyalgan PFS of M.s Matrix Pharma Reg.# 031340
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do,Republic of Korea
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2.The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification ofspecifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence Euflexxa
	Analytical method validation/verification of product	Firm has submitted analytical method validationstudies for the applied product.
	Container closure system of the drug product	Pre-filled syringe
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batchesThe accelerated stability study data is conducted at
		25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at5ºC ±3ºC / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

- The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg
- Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.
- Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministryof Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
- Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Submission by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg	Firm has submitted copy of CoPP certificate (No. 2024-D1-0199) dated 08-02- 2024 issued by Ministry of Food and Drug Safety, South Korea fo Hyal Forte Injection (pre-filled syringe). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturin site through periodic inspection every 3 years.
2.	Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.	Firm has submitted copy of NOC from M/s Shin Poong Pharmaceutical Co., Ltd. which authorises M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi,Pakistan to register their products in Pakistan. The authorization letter is issued on 29-01-2024.
3.	Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministryof Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.	Firm has submitted copy of GMP certificate (No. 2024-D1-0201) dated 08-02-2024 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. Wonsi-ro,Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosag form has been mentioned in injections.
4.	Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.	Firm has **not** submitted any written justification instead a chart is submitted which does not specify any product.

Decision: Deferred for following:

- **Justification for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.**

Case No. 05 Cases of Form 5-A

a. New cases

665.	**Name and address of Applicant**	**M/s Scilife Pharma (Pvt) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi**
	Detail of Drug Sale License	**Address:** **Validity:** **Status:**
	Name and address of manufacturer	Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
	Name and address of marketing authorization holder	
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16163: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	PAZONIB 200mg Tablet
	Composition	Each film coated tablet contains: Pazopanib (as pazopanib hydrochloride)…….200mg
	Finished Product Specification	
	Pharmacological Group	Antineoplastic agent
	Shelf life	24 months, Firm has submitted stability study data of 3 batches as per zone IV-A conditions for 24 months.
	Demanded Price	53,000
	Pack size	30's
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	• Firm has submitted copy of letter from Laboratorio Eczane Pharma to DRAP, authorizing Scilife Pharma (Pvt) Ltd to register, import, distribute and commercialize their products in Pakistan

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	
2.	Submit valid drug sale license	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
4.	Submit evidence of me-too status	
5.	Submit evidence of finished product specifications.	
6.	Submit valid, original, legalized certificate of pharmaceutical product.	
7.	Submit notarized / legalized sole agency agreement.	

	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.	
666.	**Name and address of Applicant**	**M/s Scilife Pharma (Pvt) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi**
	Detail of Drug Sale License	**Address:** **Validity:** **Status:**
	Name and address of manufacturer	Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
	Name and address of marketing authorization holder	
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16164: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	PAZONIB 400mg Tablet
	Composition	Each film coated tablet contains: Pazopanib (as pazopanib hydrochloride)…….400mg
	Finished Product Specification	
	Pharmacological Group	Antineoplastic agent
	Shelf life	24 months, Firm has submitted stability study data of 3 batches as per zone IV-A conditions for 24 months.
	Demanded Price	53,000
	Pack size	30's
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	• Firm has submitted copy of letter from Laboratorio Eczane Pharma to DRAP, authorizing Scilife Pharma (Pvt) Ltd to register, import, distribute and commercialize their products in Pakistan

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	
2.	Submit valid drug sale license	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
4.	Submit evidence of me-too status	
5.	Submit evidence of finished product specifications.	
6.	Submit valid, original, legalized certificate of pharmaceutical product.	
7.	Submit notarized / legalized sole agency agreement.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

667.	**Name and address of Applicant**	**M/s Neutro Healthcare, 22-M, Gulberg III Lahore.**

Detail of Drug Sale License	**Address:** 22-M, Gulberg III Lahore. **Validity: 16-08-2020** **Status:** License to sell drugs as distributor
Name and address of manufacturer	Zhejiang Kangle Pharmaceutical Co. Ltd. No. 555, the 8th Binhai Road, Binhai Industrial Zone, Economic Technological Development Zone, Wenzhou China.
Name and address of marketing authorization holder	Zhejiang Kangle Pharmaceutical Co. Ltd. No. 555, the 8th Binhai Road, Binhai Industrial Zone, Economic Technological Development Zone, Wenzhou China.
Name of exporting country	China
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy No. 16355: 07-03-2019
Fee including differential fee	PKR 100,000/-: 07-03-2019
Brand Name +Dosage Form + Strength	Polygeline Injection
Composition	
Finished Product Specification	
Pharmacological Group	Gelatin agent
Shelf life	24 months
Demanded Price	As per SRO
Pack size	Cleat, Colorless PP Bottles with halogenated butyl rubber stopper for injection and is sealed with plastic infusion container with aluminium plastic composite cover.
International availability	Not provided
Me-too status	Not provided
Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit valid drug sale license, since the submitted DSL is expired.	
2.	The application on Form 5-A is filled and signed by Zhejiang Kangle Pharmaceutical instead of the applicant / importer. Furthermore the name and address of importer is mentioned as Neutro Pharma (Pvt) Ltd instead of mentioning complete name and address of Neutro Health Care. Correction in Form 5-A is required along with submission of requisite fee.	
3.	Submit complete label claim of the applied product since Gelatin 500ml:3.2g (3.5%, calculated by nitrogen) is mentioned which does not represent any label claim.	
4.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
5.	Submit evidence of me-too status	
6.	Submit evidence of finished product specifications.	
7.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is conducted as per the conditions which are not recommended by ICH or WHO.	

8.	Submit valid, original, legalized certificate of pharmaceutical product.	
9.	Submit notarized / legalized sole agency agreement.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

668.	**Name and address of Applicant**	**M/s Neutro Healthcare, 22-M, Gulberg III Lahore.**
	Detail of Drug Sale License	**Address:** 22-M, Gulberg III Lahore. **Validity: 16-08-2020** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	Getwell Pharmaceuticals 474, Udyog Vihar Phase-V, Gurgaon Haryana India.
	Name and address of marketing authorization holder	Getwell Pharmaceuticals 474, Udyog Vihar Phase-V, Gurgaon Haryana India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16357: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	Pacliwel-100mg/16.7ml
	Composition	Each ml contains: Paclitaxel……..6mg
	Finished Product Specification	USP
	Pharmacological Group	Anti cancer
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	• Firm has submitted copy of letter of authorization between Getwell Pharmaceuticals and Neutro Pharma (Pvt) Ltd. Dated 19-11-2016 specifying Pacliwel 100mg/16.7ml

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit valid drug sale license, since the submitted DSL is expired.	
2.	The application on Form 5-A is filled and signed by Getwell Pharmaceutical instead of the applicant / importer. Furthermore, the name and address of importer is mentioned as Neutro Pharma (Pvt) Ltd instead of mentioning complete name and address of Neutro Health Care. Correction in Form 5-A is required along with submission of requisite fee.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
4.	Submit evidence of me-too status	
5.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	

6.	Submit valid, original, legalized certificate of pharmaceutical product.	
7.	Submit notarized / legalized sole agency agreement.	
8.	Submitted copy of letter of authorization is between Getwell Pharmaceuticals and Neutro Pharma (Pvt) Ltd, while the applicant firm is Neutro Healthcare which is a different entity. Clarification is required in this regard.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

669.	**Name and address of Applicant**	**M/s Neutro Healthcare, 22-M, Gulberg III Lahore.**
	Detail of Drug Sale License	**Address:** 22-M, Gulberg III Lahore. **Validity: 16-08-2020** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	
	Name and address of marketing authorization holder	
	Name of exporting country	
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16356: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	Teicoplanin for Injection
	Composition	Each vial contains: Teicoplanin……..0.2g
	Finished Product Specification	
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit complete application on Form 5-A, since Form 5-A is not submitted.	
	Submit valid drug sale license, since the submitted DSL is expired.	
2.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
3.	Submit evidence of me-too status	
4.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions	
5.	Submit valid, original, legalized certificate of pharmaceutical product.	
6.	Submit notarized / legalized sole agency agreement.	

	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.	
670.	**Name and address of Applicant**	**M/s Neutro Healthcare, 22-M, Gulberg III Lahore.**
	Detail of Drug Sale License	**Address:** 22-M, Gulberg III Lahore. **Validity: 16-08-2020** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	
	Name and address of marketing authorization holder	
	Name of exporting country	
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16354: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	Omeprazole sodium for Injection
	Composition	
	Finished Product Specification	
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit complete application on Form 5-A, since Form 5-A is not submitted.	
	Submit valid drug sale license, since the submitted DSL is expired.	
2.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
3.	Submit evidence of me-too status	
4.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions	
5.	Submit valid, original, legalized certificate of pharmaceutical product.	
6.	Submit notarized / legalized sole agency agreement.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

a. Deferred cases

671.	**Name and address of Applicant**	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Detail of Drug Sale License	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore.

	Validity: 21-05-2027 **Status:** License to sell drugs as distributor
Name and address of manufacturer	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
Name and address of marketing authorization holder	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
Name of exporting country	India
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy No. 16459: 07-03-2019
Fee including differential fee	PKR 50,000/-: 07-03-2019
Brand Name +Dosage Form + Strength	Dacarbazine 200mg Injection
Composition	Each vial contains: Dacarbazine as dacarbazine citrate lyophilized…….200mg
Finished Product Specification	USP
Pharmacological Group	Anticancer
Shelf life	24 months
Demanded Price	As per SRO
Pack size	As per SRO
International availability	USFDA Approved
Me-too status	Decarb Injection by Rotex Pharma
Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	
2.	Submit notarized / legalized sole agency agreement.	
3.	Submit original, legalized CoPP from the country of origin	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	Firm has now submitted submitted stability study report of three batches of drug product as per refrigerating conditions.
2.	Submit notarized / legalized sole agency agreement.	Firm has submitted copy of authorization letter.
3.	Submit original, legalized CoPP from the country of origin	Firm has submitted copy of CoPP (No 427/05/23-296) dated 22-02-2024 for Dacmed 200mg Injection which confirms free sale status as well as GMP status.

Decision: Approved as per Policy for inspection of Manufacturer abroad. Registration Board further decided that registration letter will be issued after submission of following:

- **Valid, Legalized CoPP.**
- **Valid, legalized / notarized letter of authorization.**

Case No. 05 Deferred Cases of Form 5

672.	Name and address of manufacturer/ Applicant	M/s Scilife Pharma Pvt Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi. (Contract giver) M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. (contract acceptor) (Carbapenem section)
	Brand Name + Dosage Form + Strength	Penem 1g IV Injection.
	Composition	Each Vial Contains: Meropenem ……..…1gm.
	Diary No. Date of R & I & fee	Dy. No 16168 dated 07-03-2019; Rs.50,000/- dated 07-03-2019.
	Pharmacological Group	Other beta lactam antibacterial/carbapenems.
	Type of Form	Form-5.
	Finished product Specification	USP specifications.
	Pack size & Demanded Price	1's & as per DRAP Pricing Policy.
	Approval status of product in Reference Regulatory Authorities	MERREM® IV 1gm (meropenem for injection), USFDA approved.
	Me-too status	Noopem 1gm Injection IV, Nicholas Pharmaceuticals, Reg. No. 094313.
	GMP status	Global Pharma: GMP certificate issued on 24-12-2018 on the basis of inspection conducted on 24-10-2018. Scilife Pharma: GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator	• M/s Scilife Pharma has 06 approved sections vide letter No. F. 2-4/2011-Lic (Vol-I) dated 18-06-2021. • M/s Scilife Pharma has also submitted that they have 09 approved products on contract basis.
	Decision of 312th meeting of Registration Board: Registration Board delibrated the case in detail and observed that the contract manufacturer has not performed complete product development studies, the specifications adopted by the manufacturer throughout stability studies were not according to USP and that the stability batches have also expired. Accordingly, the Board deferred for following submissions: • Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug Product manufacturer. • Scientific justification for using flow rate of 1.0ml/min for assay testing of your commercial batches since USP recommends flow rate to be 1.5ml/min, • Scientific justification for having the method of sample solution preparation for the commercial batches which is entirely different from that specified in USP monograph. • Scientific justification for having analytical method of drug product without specifying that "*sample should be hold for 1-2 hours at 25± 1°C before testing*" which is recommended in USP monograph. • Scientific justification for releasing the commercial batch of drug product and during its stability studies even after having the value of tailing factor above 1.5, since USP monograph specifies tailing factor NMT 1.5 in the system suitability requirements. • Scientific justification for using different HPLC equipment and software for the standard solution and the sample solution analysis. • Scientific justification for HPLC testing of your commercial batches using UV detector at 220nm while the USP recommends that testing be performed at 300nm. • Scientific justification for using reference / working standard having a potency of 73.91% for the analysis of commercial batches. • Scientific justification for having a master formulation containing 707mg of meropenem trihydrate blended with sodium carbonate which is equivalent to 500mg meropenem. • Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.	

- Scientific justification why complete tests as mentioned in USP monograph were not performed in pharmaceutical equivalence studies.
- Scientific justification for not performing compatability studies of the drug product with the recommended diluent.
- Scientific justification for not performing the test of sodium content and loss on drying for the analysis of commercial batches of the drug product.
- Scientific justification for using an entirely different formula for calculation of assay resultsof commercial batches from that specified in USP monograph.
- Scientific justification for not performing test of content of sodium, completeness and clarity of solution, loss on drying and sterility test during the stability studies of the product.
- Scientific justification for the results of assay test of meropenem for the batch No. 17L078 which show upward trend (i.e. increase in assay values with time) throughout the stability studies (both accelerated and real time) keeping in view the fact that the testing method was not exactly as per USP monograph, the reference standard meropenem (trihydrate) for injection was used instead of meropenem (base), the contents of sodium, as well as sodium carbonate was not determined at any time point during stability studies and loss on drying is also not performed during the stability studies.
- Scientific justification how three batches have been manufactured using 5Kg containers while each batch required 5.4Kg drug substance.
- Evidence of purchase of atomic absorption spectrophotometer including commercial invoice and Installation Qualification (IQ) and Operational Qualification (OQ) of atomic absorption.
- Submission of fee for pre-registration changes in the drug product specifcations.

Keeping in view the above, the Board decided that the submitted stability study data is not acceptable and directed the manufacturer to either perform complete product development and stability studies or submit the aforementioned data as per USP specifications and submit data accordingly. The Board further directed the manufacturer to comply USP Specifications for already registered drug products.

Response by the firm:

The applied product to be manufactured by M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad has already been approved by Registration Board in its 320th meeting. The details of the already approved product are as follows:

Applicant firm	M/s Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	**MEPEN 1g Injection IV**

Decision: Approved.

673.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi**
	Brand Name +Dosage Form + Strength	Taclorex Ointment 0.05mg/0.5mg
	Composition	Each Gram Contains: Calcipotriol as Monohydrate…0.05mg Batamethasone as Dipropionate Eq To Batamethasone…0.5mg
	Diary No. Date of R& I & fee	Dy No. 15206: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsoriatics for topical use in combination
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Caliros Ointment by Panacea Pharma
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on

		inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Revise your formulation as per the reference product along with submission of full fee of registration.
	Decision of 329th meeting of RB: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Response by the firm: Firm has submitted reference of following product: Calcipotriol/Betamethasone Sandoz 50 micrograms per g / 500 micrograms per g Ointment **(MHRA Approved)**	
	Decision: Approved.	

674.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Ezesel tablet 20mg/10mg
	Composition	Each tablet contains: Ezetimibe.....10mg Atorvastatin.....20mg
	Diary No. Date of R& I & fee	Dy. No.15806; 21-09-2017; Rs.20,000/- (21-09-2017)
	Pharmacological Group	Cholesterol absorption inhibitor/HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 14's, and 28's; As per leader price
	Approval status of product in Reference Regulatory Authorities	USFDA approved as film-coated tablets
	Me-too status (with strength and dosage form)	Atozet 10/20 tablet of M/s Hilton Pharma (Reg.#061223)
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	• Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons. • No USP or BP monograph is available for applied formulation. • Upon communication of shortcomings firm has submitted following revised form 5 with following composition: " Each film coated tablet contains: Ezetimibe.....10mg Atorvastatin as calcium trihydrate .....20mg"
	Decision of 284th meeting of Registration Board: Deferred for submission of requisite fee for change of formulation.	
	Response by the firm: Firm has submitted following fee challan: • Copy of fee challan for 5,000/- dated 03-09-2020 • Fee slip (No 277218386) for amount 2500.	
	Decision: Approved with Innovator's specifications.	

	• **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
675.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Ezesel tablet 40mg/10mg
	Composition	Each tablet contains: Ezetimibe.....10mg Atorvastatin 40mg
	Diary No. Date of R& I & fee	Dy. No.15807; 21-09-2017; Rs.20,000/- (21-09-2017)
	Pharmacological Group	Cholesterol absorption inhibitor/HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 14's, and 28's; As per leader price
	Approval status of product in Reference Regulatory Authorities	USFDA approved as film-coated tablets
	Me-too status (with strength and dosage form)	Atozet 10/40 tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	• Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons. • No USP or BP monograph is available for applied formulation. • Upon communication of shortcomings firm has submitted following revised form 5 with following composition: " Each film coated tablet contains: Ezetimibe.....10mg Atorvastatin as calcium trihydrate .....40mg"
	Decision of 284th meeting of Registration Board: Deferred for submission of requisite fee for change of formulation.	
	Response by the firm: Firm has submitted following fee challan: • Copy of fee challan for 5,000/- dated 03-09-2020 • Fee slip (No 02291274307) for amount 2500/-.	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

676.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Irbesar tablet 300mg
	Composition	Each tablet contains: Irbesartan.....300mg
	Diary No. Date of R& I & fee	Dy. No.15811; 21-09-2017; Rs.20,000/- (21-09-2017)
	Pharmacological Group	Angiotensin-II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's and 30's; As per leader price
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status (with strength and dosage form)	Arbi tablet 300mg of M/s PharmEvo

	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	The official monograph of the applied formulation is available in USP. In contrary to reference product approved by MHRA which is available as film coated tablet firm has applied for uncoated tablet.
	Decision of 284th meeting of Registration Board: Deferred for submission of revised formulation as per reference product along with requisite fee.	
	Response by the firm: Firm has submitted following: • Revised formulation with following label claim Each film coated tablet contains: Irbesartan.....300mg • Copy of fee challan for 5,000/- dated 24-03-2020 • Fee slip (No 172346722) for amount 2500/-.	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

677.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Drota tablet 40mg
	Composition	Each tablet contains: Drotaverine 40mg
	Diary No. Date of R& I & fee	Dy. No.15803; 21-09-2017; Rs.20,000/- (21-09-2017)
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	20's; As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by 3 EMA member states i.e. Poland, Hungary and Latvia as uncoated tablets
	Me-too status (with strength and dosage form)	Draza 40mg tablet of M/s Opal Lab.
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	No USP or BP monograph is available for applied formulation. • Upon communication of shortcomings firm has submitted following revised form 5 with following composition: " Each tablet contains: Drotaverine hydrochloride.....40mg"
	Decision of 284th meeting of Registration Board: Deferred for submission of requisite fee for change of formulation.	
	Response by the firm: Firm has submitted following fee challan: • Copy of fee challan for 5,000/- dated 24-08-2020 • Fee slip (No 46842382) for amount 2500/-.	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

678.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Rocycl Injection
	Composition	Each 2ml Ampoule Contains:

		Procyclidine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16847: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-Parkinson Drugs
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Xprodine Injeciton 10mg by Mass Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (SVP) (General) section. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 329th meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Response by the firm: Firm has submitted following evidence of approval **Product name:** Kemadrin 5mg/ml Solution for injection **Firm:** Accord Healthcare Limited **RRA: MHRA UK**	
	Decision: Approved.	

679.	**Name and address of manufacturer / Applicant**	**Applicant** **M/s Dyson Research Laboratories (Pvt) Ltd. (DML # 0000559)** **28-Km Ferozepur Road Lahore.** **Contract manufacturing from** **M/s Medisave Pharmaceuticals (DML # 0000681)** **Plot No.578-579 Sundar Industrial Estate Lahore.**
	Brand Name +Dosage Form + Strength	Onsetron Injection
	Composition	Each 4 ml solution contains Ondansetron (as 2HCl) …… 8 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 32983 dated 03-12-2021* Dy. No. 2442 dated 15-04-2013 Rs.50000/- dated 10-04-2013 *(Photocopy)*
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA ie approved formulation
	Me-too status	Onset by Pharmedics
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision of 333rd meeting of Registration Board: Deferred for the submission of the following: • Evidence of Section approval from Licensing Division.	

	• Latest GMP inspection report conducted within last three years. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.
	Response by the firm: Firm has submitted copy of section approval letter specifying injectable (ampoule) general section along with copy of GMP inspection report dated 21-08-2023 recommending renewal of DML.
	Decision: Approved.

Case No. 06 Miscellaneous Cases

680. Case of M/s Nortech Pharmaceuticals, Islamabad.

M/s Nortech Pharmaceuticals Islamabad has applied for following products on Form 5 on 07-03-2019.

Sr. No	Name of applicant / manufacturer	Applied product (Brand name) and composition	Details of Dy and Fee
1.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan	Norceff 1000mg Injection Each Vial Contains: Cefoperazone Sodium…500mg Sulbactam Sodium…500mg	**Form-5** Dy. No 16052 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
2.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan	Norceff 2000mg Injection Each Vial Contains: Cefoperazone Sodium…1000mg Sulbactam Sodium…1000mg	**Form-5** Dy. No 16053 dated 07-03-2019 Rs.50,000/- dated 07-03-2019

Later on the firm submitted application on Form 5F dated 02-09-2021 with same fee but with a different contract manufacturer i.e. M/s Cure Laboratories. The details of the application submitted on Form 5F are as under:

Sr. No	Name of applicant / manufacturer	Applied product (Brand name) and composition	Details of Dy and Fee
1.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad	Norceff 1000mg Injection Each Vial Contains: Cefoperazone Sodium…500mg Sulbactam Sodium…500mg	**Form-5F** Dy. No 24218 dated 02-09-2021

2.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad	Norceff 2000mg Injection Each Vial Contains: Cefoperazone Sodium…1000mg Sulbactam Sodium…1000mg	**Form-5F** Dy. No 24217 dated 02-09-2021

The application submitted on Form 5F was under evaluation while the previous application submitted on Form 5 was presented in 327th meeting of Registration Board, wherein the Board approved both products to be manufactured by M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi. Since, the initial application submitted on Form 5 has been considered and approved, while the application on Form 5F is still under evaluation therefore the case is presented before the Board for disposing off the application on Form 5F.
Submitted for consideration by the Board.

Decision: Registration Board decided to disposed off the following applications of the firm applied on Form 5F, since same formulation applied on Form 5 is already approved.

Sr. No	Name of applicant / manufacturer	Applied product (Brand name) and composition	Details of Dy and Fee
1.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad	Norceff 1000mg Injection Each Vial Contains: Cefoperazone Sodium…500mg Sulbactam Sodium…500mg	**Form-5F** Dy. No 24218 dated 02-09-2021
2.	M/s Nortech Pharmaceuticals. Plot #203, Sihala Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad	Norceff 2000mg Injection Each Vial Contains: Cefoperazone Sodium…1000mg Sulbactam Sodium…1000mg	**Form-5F** Dy. No 24217 dated 02-09-2021

Agenda of Evaluator PEC-IV

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

681.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated:30-06-2022 on the basis of evaluation conducted on 14-04-2022 and valid for 3 years.

	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section dated:30-04-2022 in which Liquid Injectable (Ampoule General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27901 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 429988899160
	The proposed proprietary name / brand name	Indrop D 300,000 IU Glass Ampoule Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Cholecalciferol……..300,000 IU
	Pharmaceutical form of applied drug	Light straw to yellow oily liquid free from extraneous matter filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	BP
	Proposed Pack size	1 x 1ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarenel by Italfarmaco of (AIFA Italy Approved)
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Xareneol 300,000IU/ml of Italfarmaco by performing quality tests Description, Identification, average fill volume, sterility, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang Province, China.		
API Lot No.	01210302VD		
Description of Pack (Container closure system)	USP Type I glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	GAA_i T1-21	GAA_i T2-21	GAA_i T3-21
Batch Size	5 Liters	5 Liters	5 Liters
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	10-09-2021	24-09-2021	27-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# Zhejiang 20030221 issued by NMPA dated: 14-07-2022 and valid till 13-07-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # 122070 + 122073, dated; 25-03-2021 cleared by DRAP (Lahore) dated: 08-04-2021 specifying Cholecalciferol batch # 01210302VD
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	UV method is applied as per BP monograph.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance(s) shall be submitted.	Analytical Method Verification of drug substance by drug product manufacturer is submitted.
3.	3.2.S.5	Submitted COA of working standard Complies with USP specification while drug substance specification Claimed Ph.EU. Clarification is required.	Mistakenly shared the working standard COA of different source, actual COA of working standard received from drug substance manufacturer is submitted.
4.	3.2.S.7.3	Submit drug substance stability studies of 3 batches.	Drug substance stability studies of 03 batches submitted.
5.	3.2.P.1	• Justify the applied formulation with BP specifications while using medium chain triglycerides oil, since BP monograph specifies ethyloleate. • Justify the use of Butylated hydroxyanisole (BHA)	• We have used ethyl oleate as recommended in BP monograph, Trial manufacturing record is submitted please verify. • We observed the color change that is why practically developed and stabilized it using BHA as anti-oxidant, Compatibility studies are also performed and product is stable.
6.	3.2.P.2.2.1	How pharmaceutical equivalence of Indrop D 300,000 IU Glass Ampoule Injection and Indrop D 300,000 IU LDPE Ampoule Injection can be same. Clarification is required.	Already submitted are the pharmaceutical equivalence specifications that looks same now pharmaceutical equivalence report is submitted.
7.	3.2.P.5.1	Particulate matter testing not the part of specifications. Clarification is required.	Particulate matter testing is included in the finish product specifications.
8.	3.2.P.5.2	Submit complete method of sterility testing.	Complete sterility testing method is submitted.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source & lot number is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

682.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated:30-06-2022 on the basis of evaluation conducted on 14-04-2022 and valid for 3 years.

	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section dated:22-06-2017 in which S.V..P (Blow fill & sealing in LDPE) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27900 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 0420453621
	The proposed proprietary name / brand name	Indrop D 300,000 IU LDPE Ampoule Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Cholecalciferol……..300,000 IU
	Pharmaceutical form of applied drug	Light straw to yellow oily liquid free from extraneous matter filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	BP
	Proposed Pack size	1 x 1ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarenel by Italfarmaco of (AIFA Italy Approved)
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Xareneol 300,000IU/ml of Italfarmaco by performing quality tests Description, Identification, average fill volume, sterility, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang Province, China.		
API Lot No.	01210302VD		
Description of Pack (Container closure system)	LDPE ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LDA_i T1-21	LDA_i T2-21	LDA_i T3-21
Batch Size	5 Liters	5 Liters	5 Liters
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	10-09-2021	24-09-2021	27-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# Zhejiang 20030221 issued by NMPA dated: 14-07-2022 and valid till 13-07-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # 122070 + 122073, dated; 25-03-2021 cleared by DRAP (Lahore) dated: 08-04-2021 specifying Cholecalciferol batch # 01210302VD
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	UV method is applied as per BP monograph.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance(s) shall be submitted.	Analytical Method Verification of drug substance by drug product manufacturer is submitted.
3.	3.2.S.5	Submitted COA of working standard Complies with USP specification while drug substance specification Claimed Ph.EU. Clarification is required.	Mistakenly shared the working standard COA of different source, actual COA of working standard received from drug substance manufacturer is submitted.
4.	3.2.S.7.3	Submit drug substance stability studies of 3 batches.	Drug substance stability studies of 03 batches submitted.
5.	3.2.P.1	• Justify the applied formulation with BP specifications while using medium chain triglycerides oil, since BP monograph specifies ethyloleate. • Justify the use of Butylated hydroxyanisole (BHA)	• We have used ethyl oleate as recommended in BP monograph, Trial manufacturing record is submitted please verify. • We observed the color change that is why practically developed and stabilized it using BHA as anti-oxidant, Compatibility studies are also performed and product is stable.
6.	3.2.P.2.2.1	How pharmaceutical equivalence of Indrop D 300,000 IU Glass Ampoule Injection and Indrop D 300,000 IU LDPE Ampoule Injection can be same. Clarification is required.	Already submitted are the pharmaceutical equivalence specifications that looks same now pharmaceutical equivalence report is submitted.
7.	3.2.P.5.1	Particulate matter testing not the part of specifications. Clarification is required.	Particulate matter testing is included in the finish product specifications.
8.	3.2.P.5.2	Submit complete method of sterility testing.	Complete sterility testing method is submitted.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source & lot number is submitted.

Decision: Deferred for evidence of approval of applied formulation in same container closure in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

683.	Name, address of Applicant / Marketing Authorization Holder	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Status of the applicant	☒Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate on the basis of evaluation conducted on 15-06-2020 and valid for 3 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of renewal of DML dated:07-07-2021 in which tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28771 dated 11-10-2022
	Details of fee submitted	Rs.75,000/- Deposit slip # 42090440956
	The proposed proprietary name / brand name	P-Cab 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…20mg
	Pharmaceutical form of applied drug	Potassium-Competitive Acid Blocker (P-CAB). WHO ATC CODE**:** A02BC08
	Pharmacotherapeutic Group of (API)	White to almost white, round, scored, biconvex, film coated Tablet.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg Tablets (PMDA Japan Approved)
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceuticals Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, P.r. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of

	(Conditions & duration of Stability studies)	drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Takecab 20mg Tablets of Takeda Pharmaceuticals by performing quality tests Identification, Weight of tablets, Thickness, Disintegration test, Dissolution, Assay. CDP has been performed against the Takecab 20mg manufactured by Takeda Pharmaceuticals in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceuticals Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, P.r. China.		
API Lot No.	20190802BD		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PC20-T001	PC20-T002	PC20-T003
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	08-02-2021	09-02-2021	09-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate #2020002 in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Jiangxi Province, P.R. China issued by ***Jiangxi API Engineering Technology Research Center*** valid upto 11-03-2025 Firm has submitted Copy of DML (No. 20160125) in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China valid upto 26-11-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # jxsg200352, dated; 26-03-2020 cleared by DRAP (Peshawar) dated: 08-04-2020 specifying Vonoprazan fumarate batch # 20190802BD
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	In BMR during dispensing of vonoprazan fumarate potency is not adjusted as potency mentioned in COA is 98.58%.	Molecular weight of Vonoprazan Fumarate is 461.5 g/mol. The correlation factor is 1.336. Hence we have used 26.72mg of Vonoprazan Fumarate per tablet, which will give 20mg of Vonoprazan per tablet
2.	3.2.S.4.2	Injection volume in the assay test of the drug substance provided by the finished product manufacturer is 20µl while that of the drug substance manufacturer is 10 µl. clarify?	The Injection volumes is 20 ul is selected for analysis due to fixed loop of 20 ul is installed in manual rheodyne of HPLC. The same procedure with 20ul is validated and the validation data is submitted
3.	3.2.S.4.3	Submitted analytical method verification report by drug product manufacturer of drug substance shows different concentration for standard and sample preparation than submitted analytical testing method of assay of drug substance. Clarification is required.	The concentration of Standard and Sample used in analytical method & validation report is same as per submitted Stability Studies calculation sheets . Therefore it is requested to consider the typographical error in Analytical Method and validation report. Revised analytical method and validation report is enclosed for your kind consideration
4.	3.2.S.5	Submitted COA of working standard Complies with USP specification while drug substance specification Claimed Ph.EU	COA of working standard submitted.
5.	3.2.S.7.3	Submit drug substance stability studies of 3 batches till shelf life.	Drug substance stability studies of 3 batches till shelf life submitted.
6.	3.2.P.2.2.1	Details of product against which pharmaceutical equivalence and Comparative dissolution conducted.	Details of product against which pharmaceutical equivalence and Comparative dissolution conducted submitted.

7.	3.2.P.5.2	Justification to be provided for the selection of dissolution parameters including dissolution media buffer (6.8) volume of dissolution medium, rpm and type of USP apparatus.	Vonoprazan is a highly soluble drug substance based on ICH Q6A, which states that the drug substance should be considered highly soluble if it meets following two conditions: 1. The dissolution profile of all strengths of the dosage form should be rapid i.e. Dissolution >80 % in 15 minutes at pH 1.2, 4.5 & 6.8. 2. The highest drug product's strength is soluble in 250mL or less of aqueous media over the pH range of 1.2 to 6.8 at 37°C ± 1°C. As per ICH Q6A, for dosage forms having drug substances falls in above conditions will be considered as highly soluble drugs and do not require development of discriminatory dissolution method / parameters. Generally, a single time point with one medium is acceptable. Comparative Dissolution Study by Genome the 'P-CAB Tablets' against the Innovator Product 'Takecab Tablets' Vonoprazan release more than 85% in all three mediums within 15minutes at 50 RPM. Also, the solubility of Vonoprazan is very high throughout the physiological pH range (1.2 to 6.8). The lowest solubility of Vonoprazan is found to be in pH 6.8 as compared to solubility in pH 1.2 (about 16.5mg/ml) & pH 4.5 (8.1mg/ml) i.e. is about 4.7 mg/ml which is greater than the highest strength divided by 250 (20mg/250=0.08mg/ml), so we selected dissolution medium having pH 6.8 as a worst-case scenario. In light of above discussion and high solubility of drug substance, discriminatory dissolution parameters are not required for Vonoprazan Tablets 10mg and 20mg. Therefore, generalized lowest 50 RMP with 900ml medium (Most common volume as per USP <1092>) was selected for release and stability studies of the drug product. As per Comparative Dissolution Study by Genome the 'P-CAB Tablets' against the Innovator Product 'Takecab Tablets' Vonoprazan release more than 85% in all three mediums within 15minutes.

			Therefore, we selected the time point i.e. 15 minutes for dissolution ***However as per USFDA review report Medium used for dissolution medium is Acetate buffer pH 4.5 while firm used phosphate buffer pH 6.8***
8.	3.2.P.8	Initiation date of stability studies not mentioned.	Submitted.

Decision: Deferred for clarification of use of phosphate buffer i.e pH 6.8 as dissolution medium while from Innovator product review documents it is evident that Acetate buffer pH 4.5 is used as dissolution medium

684.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional /revised section dated:30-11-2021 in which tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30592 dated 30-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 737411454
	The proposed proprietary name / brand name	Ondonix 8mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron Hcl Dihydrate Eq. to Ondansetron…8mg
	Pharmaceutical form of applied drug	Light orange colour oval shape, biconvex, film coated Tablet.
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s, 20’s, 30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOFRAN Tablets (USFDA Approved)
	For generic drugs (me-too status)	Ondanles 8mg Tablet of M/s Neomedix Reg# 020703
	Name and address of API manufacturer.	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Zofran 8mg Tablets of by M/s Novartis Pharma. performing quality tests Identification, Appearance, Disintegration test, Dissolution, Assay. CDP has been performed against the Zofran 8mg Tablets of by M/s Novartis Pharma in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India
API Lot No.	21ON000044
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-063-01	22SB-064-02	22SB-065-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	17-03-2022	17-03-2022	17-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 issued by Food & Drugs Control Administration, Gujrat valid till 29/05/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # EI/3012100703, dated; 22-12-2021 cleared by DRAP (Karachi) dated: 05-01-2022 specifying Ondansetron Hydrochloride batch # 21ON000044
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance submitted.
2.	3.2.P.5.4	The copies of complete analysis of three batches shall be provided	The copies of complete analysis of three batches submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

685.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd.

		44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Oral Liquid (General) section mentioned. mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28940 dated 12-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 98276743408
	The proposed proprietary name / brand name	Ondonix 4mg/5ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron Hcl Dihydrate Eq. to Ondansetron…….4mg
	Pharmaceutical form of applied drug	Light orange colour oval shape, biconvex, film coated Tablet.
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP
	Proposed Pack size	30ml, 60ml, 50ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOFRAN Oral solution of (USFDA Approved)
	For generic drugs (me-too status)	Ondanles 4mg/5ml Oral solution of M/s Neomedix Reg# 066472
	Name and address of API manufacturer.	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Onseron Solution 4mg/5ml of by M/s Indus Pharma. performing quality tests Identification, Appearance, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India		
API Lot No.	21ON000044		
Description of Pack (Container closure system)	Amber glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-019-01	22SB-020-02	22SB-021-03
Batch Size	2400ml(40bottles)	2400ml(40bottles)	2400ml(40bottles)
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	23-02-2022	23-02-2022	23-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 issued by Food & Drugs Control Administration, Gujrat valid till 29/05/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # EI/3012100703, dated; 22-12-2021 cleared by

		DRAP (Karachi) dated: 05-01-2022 specifying Ondansetron Hydrochloride batch # 21ON000044
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	2.3.R.1.1	• As mixing is a critical step and batch is prepared in beaker by hand mixer than how it is ensured that uniform mixing is done. • Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.
2.	3.2.S.4.3	Submitted analytical method verification report by drug product manufacturer of drug substance shows different concentration than submitted analytical testing method of assay of drug substance.
3.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with Sucralose shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
4.	3.2.P.5.1 & 3.2.P.5.4	Deliverable volume is not part of specification as specified in USP monograph.. Clarification is required.
5.	3.2.P.5.2	Concentration of sample preparation is not as per USP monograph. Clarification is required.
6.	3.2.P.4.4	Composition of the Drug Product includes Sorbitol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit CoA's by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

686.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Dry Powder Injection (General) section mentioned.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28939 dated 12-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 5040866617
	The proposed proprietary name / brand name	Colmixin 2 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…2MIU
	Pharmaceutical form of applied drug	Powder for Solution for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial, polymyxins.
	Reference to Finished product specifications	USP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Powder for Solution for Injection by Teva UK Limited of (MHRA Approved)
	For generic drugs (me-too status)	Nogotex injection 3MIU of M/s Nabiqasim Industries Reg# 110206
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Colomycin Injection 2 MIU of Teva UK limited performing quality tests Identification, Appearance, pH, Loss on drying , Free colistin, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.		
API Lot No.	CMS2106004		
Description of Pack (Container closure system)	10ml clear tubular glass vial Type-1		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-252-01	21SB(B)-253-02	21SB(B)-254-03
Batch Size	500 Vial	500 Vial	500 Vial
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	24-11-2021	24-11-2021	24-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Written confirmation for active substance to EU #FJ00006 to M/s Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309 Valid upto 21-09-2022.The certificate confirms that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.2	Label claim of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications i.e mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams with requisit fee.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	3.2.S.4.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81>
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
5.	3.2.S.5.4	As per USP monograph Test for free colistin not performed, Clarification is required
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
7.	3.2.P.5.4	Copies of complete analysis of three batches shall be provided.
8.	3.2.P.5.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81> MICROBIAL ASSAYS Justify your sample preparation for assay in Analytical testing method with reference to USP monograph
9.	3.2.P.5.3	Analytical Method Verification studies performance is not in accordance to USP General Chapter <81> —MICROBIAL ASSAYS
10.	3.2.P.8	• Submit legible form of import documents • In submitted stability studies performance of microbial Assay is different than USP General Chapter <81> of MICROBIAL ASSAYS • Concentration of S_1-S_5 and U_3 are different than their own method

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

687.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Oral liquid (General) section mentioned.
	Status of application	☒ New Drug Product (NDP)

		☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30586 dated 30-10-2022
	Details of fee submitted	Rs.75,000/- Deposit slip # 89066911776
	The proposed proprietary name / brand name	Pascozl 40mg/ml Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml (after reconstitution) contains: Posaconazole……40mg
	Pharmaceutical form of applied drug	White colour suspension
	Pharmacotherapeutic Group of (API)	Antimycotics Drugs (ATC code: J02AC04)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NOXAFIL Oral suspension by Merck Sharp & Dhome of (USFDA Approved)
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s BrightGene Pharmaceutical Co., Ltd. Address: No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Noxafil 40mg/ml Oral suspension by Merck Sharp & Dhome (UK) limited performing quality tests Identification, Appearance, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s BrightGene Pharmaceutical Co., Ltd. Address: No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China		
API Lot No.	SPO-I-211003		
Description of Pack (Container closure system)	Amber glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-029-01	22SB-030-02	22SB-031-03
Batch Size	33 bottles	33 bottles	33 bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-03-2022	08-03-2022	08-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.2	In label claim Powder for suspension applied while in Reference regulatory Authority Oral Liquid Suspension is available.

2.	1.5.4	Pack size 60s, 90s, 105s, 120s applied while applied formulation is suspension (Liquid form)
3.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
4.	2.3.A.1	Submit evidence of achiral HPLC used in testing of drug product.
5.	2.3.R.1.1	• As mixing is a critical step and batch is prepared in beaker by hand mixer than how it is ensured that uniform mixing is done. • Scientific rationale for selecting the batch size of 33 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.
6.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
7.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
8.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
9.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with Sucralose shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
10.	3.2.P.2.2.1	The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 are not submitted.
11.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
12.	3.2.P.4.4	Composition of the Drug Product includes Glycerin. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit CoA's by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.
13.	3.2.P.5.2	Submit complete analytical procedures used for testing the drug product
14.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.
15.	3.2.P.8	Documents for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

688.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 37509 dated 22-12-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 256242185
	The proposed proprietary name / brand name	**Fineron Tablet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Finerenone……..…..10mg
	Pharmacotherapeutic Group of (API)	Diuretics, aldosterone antagonists.
	Pharmaceutical form of applied drug	Red color, spindle shaped coated tablet, both sides are plain.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's, 14's, 20's & 28's tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Kerendia Tablet (Finerenone) 10mg is registered and being marketed by Bayer AG, Germany (EMA and FDA Approved).
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 1, Yunan Street, Kaifeng, Henan Province, CN-475003, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Kerendia Tablet 10mg (Finerenone) is being marketed by Bayer AG, Germany by performing quality tests Description, Identification, Assay, Disintegration, Dissolution,). CDP has been performed against the same brand that is Kerendia Tablet 10mg (Finerenone) is being marketed by Bayer AG, Germany in Acid media (pH 1.0-1.2) 0.01N HCl & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 1, Yunan Street, Kaifeng, Henan Province, CN-475003, China.		
API Lot No.	HF220120		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	587DS01	587DS02	587DS03
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	09-07-2022	09-07-2022	09-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on 26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. HA20190069 issued by NMPA china issued dated:29-09-2019 and valid till 28-09-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 3, form 7 and Form 6 [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-286489875364 issued on 06/04/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 05/04/2024 was provided.

		Firm has submitted Commercial Invoice # IN20220311A02 dated: 11-03-2022 specifying 250g of Finerenone batch # HF220120.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.4	• Specification by drug substance manufacturer for particle size in 3.2.S.4.1 and COA are different. Justify. • In COA of drug substance by drug product manufacturer limits for particle size should be mentioned instead of complies.	• We have set limit of particle size distribution for product development i.e. D90<30 micron. We also receive particle size report prior to shipment of sample from manufacturer having psd of D90: 25.364µm. Same is enclosed. Revise MOA by drug substance manufacturer for particle size having acceptance limit of D90<30 micron is enclosed. • Revise COA with results of particle size and particle size report is enclosed.
2.	3.2.P.2.2.1	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence.	• We have done uniformity of dosage unit for reference product to incorporate in Pharmaceutical Equivalence Report. • Revise Pharmaceutical Equivalence Report ,Raw Data/Chromatograms, Audit Trail reports are enclosed
3.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Form 6 (License to import Drugs for clinical Trial, Examination, Tests or Analysis submitted

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

689.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 37510 dated 22-12-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 266874673
	The proposed proprietary name / brand name	**Fineron Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Finerenone……..…..20mg
	Pharmacotherapeutic Group of (API)	Diuretics, aldosterone antagonists.
	Pharmaceutical form of applied drug	Red color, spindle shaped coated tablet, both sides are plain.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's, 14's, 20's & 28's tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Kerendia Tablet (Finerenone) 20mg is registered and being marketed by Bayer AG, Germany (EMA and FDA Approved).
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 1, Yunan Street, Kaifeng, Henan Province, CN-475003, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5% for 24 months Accelerated: 40°C ± 2°C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Kerendia Tablet 20mg (Finerenone) is being marketed by Bayer AG, Germany by performing quality tests Description, Identification, Assay, Disintegration, Dissolution,). CDP has been performed against the same brand that is Kerendia Tablet 20mg (Finerenone) is being marketed by Bayer AG, Germany in Acid media (pH 1.0-1.2) 0.01N HCl & Acetate buffer 4.5pH , Phosphate Buffer (pH 6.8) and Acetate buffer 4.5pH with 0.1% Tween 20 . The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 1, Yunan Street, Kaifeng, Henan Province, CN-475003, China.		
API Lot No.	HF220120		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	588DS01	588DS02	588DS03
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	09-07-2022	09-07-2022	09-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on 26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. HA20190069 issued by NMPA china issued dated:29-09-2019 and valid till 28-09-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 3, form 7 and Form 6 [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-286489875364 issued on 06/04/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 05/04/2024 was provided. Firm has submitted Commercial Invoice # IN20220311A02 dated: 11-03-2022 specifying 250g of Finerenone batch # HF220120.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.4	• Specification by drug substance manufacturer for particle size in 3.2.S.4.1 and COA are different. Justify. • In COA of drug substance by drug product manufacturer limits for particle size should be mentioned instead of complies.	• We have set limit of particle size distribution for product development i.e. D90<30 micron. We also receive particle size report prior to shipment of sample from manufacturer having psd of D90: 25.364µm. Same is enclosed. Revise MOA by drug substance manufacturer for particle size having acceptance limit of D90<30 micron is enclosed. • Revise COA with results of particle size and particle size report is enclosed.
2.	3.2.P.2.2.1	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence.	• We have done uniformity of dosage unit for reference product to incorporate in Pharmaceutical Equivalence Report. • Revise Pharmaceutical Equivalence Report ,Raw Data/Chromatograms, Audit Trail reports are enclosed
3.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Form 6 (License to import Drugs for clinical Trial, Examination, Tests or Analysis submitted

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

690.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33179: 18-11-2022
	Details of fee submitted	PKR 50,000/- : Deposit slip # 2049209 PKR 25,000/- : Deposit slip # 4525805072
	The proposed proprietary name / brand name	**Gabica CR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Pregabalin…….82.5mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	14's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
1.	1.6.5	In translation of DML Orient Pharmaceutical Co., Ltd. is mentioned while in your certificate Aurisco Pharmaceutical Co., Ltd is mentioned.	Please refer to Annexure 1 for copy of DML of Aurisco Pharmaceutical Co., Ltd., China with its translation.
2.	3.2.S.4.3	Accuracy parameter is not performed in analytical method verification of drug substance by drug product manufacturer.	Analytical Method Verification studies as per BP monograph including system suitability, specificity, linearity, repeatability and range performed by the Drug Product manufacturer. Further, with reference to ICH Guidelines "VALIDATION OF ANALYTICAL PROCEDURES: TEXT AND METHODOLOGY Q2 (R1)" it is mentioned in section 4.1.1 Drug Substance "accuracy may be inferred once precision, linearity and specificity have been established". This is bring to your kind attention that since we have performed method verification studies as per ICH Q2 (R1) therefore, requirement of accuracy is not applicable. ***Firm said that at the time of stability batch manufacturing, our specification for Pregabalin API was In-house. Stability manufacturing done in November and December 2019 while they are submitting Analytical method verification as per BP of July 2019 and***

			specification of drug substance pregabalin as per BP submitted on which mentioned effective date 14-02-2024
3.	3.2.S.4.4	Pregabalin drug substance is available in pharmacopeia than how inhouse specifications are applied on drug substance by drug product manufacturer.	This is to bring to your kind information that at the time of stability batch manufacturing, our specification for Pregabalin API was In-house. Now, we have revised the specifications of Pregabalin API from In-house to BP. Please refer to updated Pregabalin API specifications as per BP monograph. Please note that at the time of commercialization of Gabica CR Tablets, we will use BP specifications for testing of Pregabalin API. ***However pregabalin Drug substance is available in BP 2017 and stability batches manufacture in 2019 No testing of drug substance as per BP submitted.***
4.	3.2.P.2.2.1	Results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted.	Results of quality tests (mentioned in Section 3.2.P.5.1) are provided in tabular form in comparison with innovator products for 'Pregabalin CR Tablets 82.5mg & 165mg'.

Justification by firm: This is to bring to your kind information that the lot of Pregabalin API used in manufacturing of stability batches was received in October 2019. At that time, our commercial specification for testing of Pregabalin API was In-House and accordingly we have submitted complete drug substance part as per In-House Specifications.

API Method Verification studies were performed in July 2019 & after that TAP (Transfer of Analytical Procedure) was performed from our R&D Lab to QC Lab. Currently, we are using BP Specification for Pregabalin API.

We hope that the above provided justification will suffice the requirement of your good office and we look forward for your kind consideration and early approval of our applied products '**Gabica CR Tablets 82.5mg & 165mg'**.

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

691.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33180: 18-11-2022
	Details of fee submitted	PKR 50,000/- : Deposit slip # 2049210 PKR 25,000/- : Deposit slip # 446929244359
	The proposed proprietary name / brand name	**Gabica CR 165mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Pregabalin…….165mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	14's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
5.	1.6.5	In translation of DML Orient Pharmaceutical Co., Ltd. is mentioned while in your certificate Aurisco Pharmaceutical Co., Ltd is mentioned.	Please refer to Annexure 1 for copy of DML of Aurisco Pharmaceutical Co., Ltd., China with its translation.
6.	3.2.S.4.3	Accuracy parameter is not performed in analytical method verification of drug substance by drug product manufacturer.	Analytical Method Verification studies as per BP monograph including system suitability, specificity, linearity, repeatability and range performed by the Drug Product manufacturer. Further, with reference to ICH Guidelines "VALIDATION OF ANALYTICAL PROCEDURES: TEXT AND METHODOLOGY Q2 (R1)" it is mentioned in section 4.1.1 Drug Substance "accuracy may be inferred once precision, linearity and specificity have been established". This is bring to your kind attention that since we have performed method verification studies as per ICH Q2 (R1) therefore, requirement of accuracy is not applicable. ***Firm said that at the time of stability batch manufacturing, our specification for Pregabalin API was In-house. Stability manufacturing done in November and December 2019 while they are submitting Analytical method verification as per BP of July 2019 and specification of drug substance pregabalin as per BP submitted on which mentioned effective date 14-02-2024***
7.	3.2.S.4.4	Pregabalin drug substance is available in pharmacopeia than how inhouse specifications are applied on drug substance by drug product manufacturer.	This is to bring to your kind information that at the time of stability batch manufacturing, our specification for Pregabalin API was In-house. Now, we

			have revised the specifications of Pregabalin API from In-house to BP. Please refer to updated Pregabalin API specifications as per BP monograph. Please note that at the time of commercialization of Gabica CR Tablets, we will use BP specifications for testing of Pregabalin API. ***However pregabalin Drug substance is available in BP 2017 and stability batches manufacture in 2019 No testing of drug substance as per BP submitted.***
8.	3.2.P.2.2.1	Results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted.	Results of quality tests (mentioned in Section 3.2.P.5.1) are provided in tabular form in comparison with innovator products for 'Pregabalin CR Tablets 82.5mg & 165mg'.

Justification by firm: This is to bring to your kind information that the lot of Pregabalin API used in manufacturing of stability batches was received in October 2019. At that time, our commercial specification for testing of Pregabalin API was In-House and accordingly we have submitted complete drug substance part as per In-House Specifications.

API Method Verification studies were performed in July 2019 & after that TAP (Transfer of Analytical Procedure) was performed from our R&D Lab to QC Lab. Currently, we are using BP Specification for Pregabalin API.

We hope that the above provided justification will suffice the requirement of your good office and we look forward for your kind consideration and early approval of our applied products '**Gabica CR Tablets 82.5mg & 165mg'**.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

692.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited. B-23-C, S.I.T.E. Karachi
	Name, address of Manufacturing site.	M/s AGP Limited. B-23-C, S.I.T.E. Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32254: 10-11-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 959152449268
	The proposed proprietary name / brand name	**Analar 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Tizanidine as Hcl…….4mg

	Pharmacotherapeutic Group of (API)	Skeletal muscle Relaxant (alpha-2-adrenergic agonist)
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Zanaflex, tablets of USFDA Approved.
	For generic drugs (me-too status)	Tandolax 4mg Tablet M/s High-Q Pharmaceuticals
	Proposed Pack size and Proposed unit price	1 x 10's As per SRO

Evaluation by PEC (No. IV):

S.No	Shortcoming	Reply
1.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Firm has submitted copy of GMP certificate of the firm based on evaluation dated 12-06-2023 and valid for 2 years.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

693.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31782: 04-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 78466107120
	The proposed proprietary name / brand name	**Zoblin-XR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Pregabalin……..82.5mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	As per SRO As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP Certificate has been submitted
2.	1.5.2	Revise your label claim as per Innovator product.	Label claim has been updated according to innovator's product. Each Extended Release Film coated Tablet Contains: Pregabalin…….82.5mg

3.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid drug manufacturing license and Valid) Good Manufacturing Practice (GMP) certificate of the drug Substance manufacturer has been attached here.
4.	3.2.S.4.3	Accuracy parameter is not performed in analytical method verification of drug substance by drug product manufacturer.	We have performed accuracy parameter for drug substance. The analytical method verification report along with its summery is attached.
5.	3.2.P.2.2.1	Details of product against which pharmaceutical Equivalence and CDP conducted.	Details of product against pharmaceutical equivalence and CDP conducted is: LYRICA CR 82.5mg Batch No, 079983
6.	3.2.P.5.1	Justification is required for not adopting all the dissolution time points as recommended by Innovator Product.	We have followed the dissolution time points as per drug product specifications recommended by innovator Lyrica CR.
7.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of applications with stability study data is submitted

Decision: Approved with innovator's specification with following label claim:
Each Extended Release Film coated Tablet Contains:
Pregabalin…….82.5mg
The firm shall submit fee of Rs. 7,500/- for revision of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

694.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32257: 10-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 63482775333
	The proposed proprietary name / brand name	**Zoblin-XR 165mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Pregabalin……..165mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	As per SRO As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
8.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP Certificate has been submitted
9.	1.5.2	Revise your label claim as per Innovator product.	Label claim has been updated according to innovator's product. Each Extended Release Film coated Tablet Contains: Pregabalin…….165mg
10.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid drug manufacturing license and Valid) Good Manufacturing Practice (GMP) certificate of the drug Substance manufacturer has been attached here.
11.	3.2.S.4.3	Accuracy parameter is not performed in analytical method verification of drug substance by drug product manufacturer.	We have performed accuracy parameter for drug substance. The analytical method verification report along with its summery is attached.
12.	3.2.P.2.2.1	Details of product against which pharmaceutical Equivalence and CDP conducted.	Details of product against pharmaceutical equivalence and CDP conducted is: LYRICA CR 165mg Batch No, 079982
13.	3.2.P.5.1	Justification is required for not adopting all the dissolution time points as recommended by Innovator Product.	We have followed the dissolution time points as per drug product specifications recommended by innovator Lyrica CR.
14.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of applications with stability study data is submitted

Decision: Approved with innovator's specification with following label claim:
Each Extended Release Film coated Tablet Contains:
Pregabalin…….165mg
The firm shall submit fee of Rs. 7,500/- for revision of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

695.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31783: 04-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 36059638
	The proposed proprietary name / brand name	**Zoblin-XR 330mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Pregabalin……..330mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	As per SRO As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
15.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP Certificate has been submitted
16.	1.5.2	Revise your label claim as per Innovator product.	Label claim has been updated according to innovator's product. Each Extended Release Film coated Tablet Contains: Pregabalin…….330mg
17.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid drug manufacturing license and Valid) Good Manufacturing Practice (GMP) certificate of the drug Substance manufacturer has been attached here.
18.	3.2.S.4.3	Accuracy parameter is not performed in analytical method verification of drug substance by drug product manufacturer.	We have performed accuracy parameter for drug substance. The analytical method verification report along with its summery is attached.
19.	3.2.P.2.2.1	Details of product against which pharmaceutical Equivalence and CDP conducted.	Details of product against pharmaceutical equivalence and CDP conducted is: LYRICA CR 330mg Batch No, 078984.
20.	3.2.P.5.1	Justification is required for not adopting all the dissolution time points as recommended by Innovator Product.	We have followed the dissolution time points as per drug product specifications recommended by innovator Lyrica CR.
21.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of applications with stability study data is submitted

Decision: Approved with innovator's specification with following label claim:
Each Extended Release Film coated Tablet Contains:
Pregabalin…….330mg
The firm shall submit fee of Rs. 7,500/- for revision of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

696.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd.

		Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39367: 29-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 5204595676
	The proposed proprietary name / brand name	**Tofanib 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib as Citrate…….5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	XELJANZ Tablets of , USFDA Approved.
	For generic drugs (me-too status)	Tofacnet Tablets of M/s Macter International Limited
	Proposed Pack size and Proposed unit price	As per SRO As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP certificate has been submitted.
2.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.	We used Polymorphic A crystalline form of Tofacitinib Citrate.
3.	3.2.S.4.2	In standard preparation and Sample solution Quantity of Tofacitinib Citrate is written as proper quantity. Clarify what is proper quantity.	The proper quantity in standard and sample preparations is 20mg of tofacitinib citrate which is dissolved in 25ml of diluent. Further dilute these solutions into 50ml with diluent to obtained 0.08mg/mL concentrations of tofacitinib citrate. Standard analytical procedure attached for further clarification.
4.	3.2.S.4.3	Submitted analytical method verification of drug substance by drug product manufacturer is of different substance than applied. Clarification is required.	We performed analytical method verification of drug substance according to the drug product manufacturer. Analytical method verification report attached for further clarification.
5.	3.2.S.4.5	• Justification is required for not performing Particle size distribution by both drug substance manufacturer and drug product manufacturer. • Justification is required for Performance of LOD instead of Water content as Drug substance specification includes water content.	• The manufacturer of drug product performed particle size distribution test as in the mentioned updated manufacturer COA of Tofacitinib Citrate and we take the parameter of particle size distribution of drug manufacturer as reference. • We perform LOD test according to the manufacturer method as mentioned in SAP, in drug substance specifications, mistakenly written water content rather than LOD. Manufacturing Unit Standard use analytical procedure attached clarification. for further

6.	3.2.P.2.2.1	Details of product against which pharmaceutical Equivalence and CDP conducted.	Details of product against pharmaceutical Equivalence and CDP conducted. XELGANZ 5mg Batch No: FD7205
7.	3.2.P.5.2	Justify the variation of dissolution parameters from that recommended by Innovator product	We performed dissolution test according to the FDA guidelines 2018 and the parameters were selected according to the recommended in the guideline.
8.	3.2.P.5.3	Justify your Standard preparation in analytical method validation.	For standard preparation we taken 16.1mg of tofacitinib citrate which is equivalent to 10mg of tofacitinib base, and dissolve to 25mL with diluent. Then further dilute 2mL in 25mL with diluent. The final concentration is 0.5152mg/mL of tofacitinib citrate which is equivalent to 0.032mg/mL of tofacitinib base.
9.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.	We performed all the test according to the Innovator's product except impurities and we used impurities parameter of drug manufacturer as reference.
10.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm.	Reference of previous approval of applications with stability study data of the firm has been submitted.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

697.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39368: 29-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 282807414
	The proposed proprietary name / brand name	**Tofanib 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib as Citrate…….10mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	XELJANZ Tablets of , USFDA Approved.
	For generic drugs (me-too status)	Tofacnet Tablets of M/s Macter International Limited
	Proposed Pack size and Proposed unit price	As per SRO As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply

1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP certificate has been submitted.
2.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.	We used Polymorphic A crystalline form of Tofacitinib Citrate.
3.	3.2.S.4.2	In standard preparation and Sample solution Quantity of Tofacitinib Citrate is written as proper quantity. Clarify what is proper quantity.	The proper quantity in standard and sample preparations is 20mg of tofacitinib citrate which is dissolved in 25ml of diluent. Further dilute these solutions into 50ml with diluent to obtained 0.08mg/mL concentrations of tofacitinib citrate. Standard analytical procedure attached for further clarification.
4.	3.2.S.4.3	Submitted analytical method verification of drug substance by drug product manufacturer is of different substance than applied. Clarification is required.	We performed analytical method verification of drug substance according to the drug product manufacturer. Analytical method verification report attached for further clarification.
5.	3.2.S.4.5	• Justification is required for not performing Particle size distribution by both drug substance manufacturer and drug product manufacturer. • Justification is required for Performance of LOD instead of Water content as Drug substance specification includes water content.	• The manufacturer of drug product performed particle size distribution test as in the mentioned updated manufacturer COA of Tofacitinib Citrate and we take the parameter of particle size distribution of drug manufacturer as reference. • We perform LOD test according to the manufacturer method as mentioned in SAP, in drug substance specifications, mistakenly written water content rather than LOD. Manufacturing Unit Standard use analytical procedure attached clarification. for further
6.	3.2.P.2.2.1	Details of product against which pharmaceutical Equivalence and CDP conducted.	Details of product against pharmaceutical Equivalence and CDP conducted. XELGANZ 10mg Batch No: GP7304.
7.	3.2.P.5.2	Justify the variation of dissolution parameters from that recommended by Innovator product	We performed dissolution test according to the FDA guidelines 2018 and the parameters were selected according to the recommended in the guideline.
8.	3.2.P.5.3	Justify your Standard preparation in analytical method validation.	For standard preparation we taken 16.1mg of tofacitinib citrate which is equivalent to 10mg of tofacitinib base, and dissolve to 25mL with diluent. Then further dilute 2mL in 25mL with diluent. The final concentration is 0.5152mg/mL of tofacitinib citrate which is equivalent to 0.032mg/mL of tofacitinib base.
9.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.	We performed all the test according to the Innovator's product except impurities and we used impurities parameter of drug manufacturer as reference.
10.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm.	Reference of previous approval of applications with stability study data of the firm has been submitted.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

698.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 366: 04-01-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 25226483
	The proposed proprietary name / brand name	**Rheumatib 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib as Citrate…….10mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	XELJANZ Tablets of , USFDA Approved.
	For generic drugs (me-too status)	Tofajak Tablets 5mg of M/s Hiranis Pharmaceuticals
	Proposed Pack size and Proposed unit price	7's, 10's, 14's, 20's, 28's and 30's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.
4.	3.2.S.4.3	Accuracy parameter in Analytical method verification of drug substance by drug product manufacturer is not performed
5.	3.2.S.4.5	Justification is required for Performance of LOD instead of Water content as Drug substance specification includes water content.
6.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product as mentioned in section 3.2.P.5.1 of this application . • Submit detail results of comparative dissolution profile.
7.	3.2.P.5.2	Justify the variation of dissolution parameters from that recommended by Innovator product
8.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

699.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd.

		E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32893: 16-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 316456250349
	The proposed proprietary name / brand name	**Unigab CR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film coated Tablet Contains: Pregabalin……..82.5mg
	Pharmacotherapeutic Group of (API)	Antiepileptic/Anticonvulsant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	10's, 30's As per SRO
Evaluation by PEC (No. IV):		
Decision: Approved with innovator's specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
700.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32894: 16-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 914278134861
	The proposed proprietary name / brand name	**Unigab CR 165mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film coated Tablet Contains: Pregabalin…….165mg
	Pharmacotherapeutic Group of (API)	Antiepileptic/Anticonvulsant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	

	Proposed Pack size and Proposed unit price	10's, 30's As per SRO
Evaluation by PEC (No. IV):		
Decision: Approved with innovator's specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
701.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32895: 16-11-2022
	Details of fee submitted	PKR 75,000/- : Deposit slip # 5618981519
	The proposed proprietary name / brand name	**Unigab CR 330mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film coated Tablet Contains: Pregabalin……...330mg
	Pharmacotherapeutic Group of (API)	Antiepileptic/Anticonvulsant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	10's, 30's As per SRO
Evaluation by PEC (No. IV):		
Decision: Approved with innovator's specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
702.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32892: 16-11-2022

	Details of fee submitted	PKR 75,000/- : Deposit slip # 83852832501
	The proposed proprietary name / brand name	**Unigab 20mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Pregabalin……..20mg
	Pharmacotherapeutic Group of (API)	Antiepileptic/Anticonvulsant
	Reference to Finished product specifications	Innovator's
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Lyrica oral solution 20mg/ml(Pregabalin) Manufactured by: Pfizer USA (FDA Approved)
	For generic drugs (me-too status)	
	Proposed Pack size and Proposed unit price	473ml, 200ml, 120ml As per SRO

Evaluation by PEC (No. IV):

S.No		Shortcoming	Reply
1.	3.2.P.8	According to the innovator review report stability of innovator drug product has been performed at the ICH alternative storage conditions of 30°C ± 2°C /at 35% RH, ± 5% and 40°C ± 2°C /at 25% RH, ± 5%,in HDPE container, justify for not performing the stability of applied drug product at the alternative storage condition as per the ICH guideline.	• We have conducted stability studies of Unigab 20mg/ml Oral Solution at ICH Zone IVA condition (Long term: 30°C±2°C/ 65%RH±5% & Accelerated: 40°C±2°C/ 75%RH±5%) while the product packaged in HDPE bottles **(**impermeable container) as follows: • According to (ICH)) guidelines, Q1A(R2) the High-Density Polyethylene (HDPE) container used for storing the Product is not considered a semipermeable container • Similarly, as per "Asean Guideline On stability of Drug Product" (R1) section 4.7.2 it is stated : Generally considered moisture-impermeable containers include glass ampoules, aluminium/aluminium blisters, High Density Polyethylene (HDPE) or glass bottles fitted with metal or HDPE closures.(attached) On the basis of above cited references we have conducted stability studies according to ICH Zone –IVA condition. However we will perform water loss test on commercial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

703.	Name, address of Applicant / Marketing Authorization Holder	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd 28-km Ferozepur Road, Lahore – Pakistan
	Name, address of Manufacturing site.	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd 28-km Ferozepur Road, Lahore – Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2550: 26-01-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 30161079925
	The proposed proprietary name / brand name	**Obeticol Tablet 5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Obeticholic Acid.....5 mg
	Pharmacotherapeutic Group of (API)	Farnesoid X Receptor Agonist
	Reference to Finished product specifications	Manufacturer specification
	The status in reference regulatory authorities	OCALIVA 5mg film coated tablets USFDA
	For generic drugs (me-too status)	Obliva 5mg Tablet of M/s Hilton Pharma, Karachi
	Proposed Pack size and Proposed unit price	10's, 20's & 30's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP inspection report of the manufacturing unit issued within the three years is submitted.
2.	1.5.5	Submit correct Pharmacological group	Obeticholic Acid is a Farnesoid X Receptor Agonist for Primary Biliary Cholangitis.
3.	1.5.6	You have applied Manufacture's specifications so submit following requirements in the light of Guidance Document Regarding Application of Drug Product Specifications: a. Analytical method development and validation report including performance of accuracy, precision, specificity,linearity, ruggedness and robustress parameters as per ICH Q2 (It2) guideline for assay, dissolution and impurities (as applicable),against innovator's product b. The proposed analytical method shall be based upon similar principles (e.g.,chromatographic, spectroscopic, titration) as declared by the innovator drug product literature. c. Comparison between proposed drug product specifications and available innovator's/Reference drug product specifications wherein it could be established that proposed specifications are either equivalent or stringent than the innovator's/ Reference specifications. d. Comparative pharmaceutical equivalence against innovator's/Reference product including comparative dissolution profiling (if applicable).	The Product is of innovator specification and is tested against **Ocaliva Tablets** which is the innovator Product.

		e. Stability study data of the product for accelerated and time period (using stability indicating method) as per the guidelines approved by Registration Board.	
4.	1.6.5 (a)	Two different drug substance manufacturer are submitted in section 1.6.5 and in section 3.2.S.2.1. Clarify from which source drug substance is used for manufacturing of stability batches.	Changzhou Pharmaceutical Factory and Nantong Chanyoo Pharmatech Co., Ltd are the same entities. As Cahngzhou Pharmaceutical Factory owned Nantong Chanyoo Pharmatech Co., Ltd dated 24-07-2014
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Drug Manufacturing License of Nantong Chanyoo Pharmatech Co., Ltd submitted.
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided submitted.
6.	3.2.S.4.1	Please justify that why sulphated ash, heavy metals, palladium test ,particle size distribution, solid state form (XRPD), and microbial limits are not included in Drug substance testing specification while same are part of Innovator specifications.	Particle Size distribution and XPRD will be obtained from Drug Substance manufacturer and Sulphated Ash, Heavy metals and Microbial Limits are updated in Analytical method and will be included in commercial Batch. Analytical method of drug substance by drug Product manufacturer is attached**.**
7.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted**.**
8.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted	Analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
9.	3.2.S.4.4	Provide Certificate of Analysis (CoA) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical ingredient manufacture	Certificate of Analysis (COA) of Drug Substance by Drug Product manufacturer along with Certificate of Analysis (COA) of the same batch from Drug Substance Active Pharmaceutical ingredient manufacturer are submitted.
10.	3.2.S.5	Submitted COA of working standard is from M/s Changzhou Pharmaceutical Factory while details of drug substance submitted from M/s Nantong Chanyoo Pharmatech.	M/s Changzhou Pharmaceutical Factory and M/s Nantong Chanyoo Pharmatech are the same entity; therefore, the provided working Standard COA of the drug substance for the respective batch of API is correct. Statement of Owner ship and Working Standard COA of Drug Substance manufacturer are attached

11.	3.2.S.7	Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	Stability studies at recommended storage conditions of 5°C ± 3°C for drug substance submitted.
12.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document. • Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	• The Pharmaceutical Equivalence study include complete testing of drug product and Reference Product. Pharmaceutical Equivalence report is submitted. • According USFDA Guideline the medium used for Obeticholic Acid Tablets is "0.08% polysorbate 80 in 50mM sodium phosphate dibasic buffer, pH 6.8". and the same is used by drug Product Manufacture. Polysorbate is used by drug product manufacturer in composition of phosphate buffer which is evident from the method of dissolution submitted under 3.2.P.5.1
13.	3.2.P.3.4	Particle size distribution is not conducted by bot drug substance manufacturer and drug product manufacturer and Particle size distribution plays a critical role in the content uniformity and dissolution of the tablets, so what steps has been taken by Drug product manufacturer to confirm the **"**Particle size control**"** of active substance in formulation.	Particle size distribution data will be obtained from the drug substance manufacturer for commercial imports. Furthermore, the dissolution test is an important control for particle size distribution. For commercial batches, we will conduct comparative dissolution tests for control purposes. Additionally, a third-party particle size test can be included for commercial batches
14.	3.2.P.5.1	Please justify that why test for water content and microbial limits form have not been included in stability studies while it is included in innovator product specification	Water Content and Microbial limits has been updated in Analytical method.
15.	3.2.P.5.2	Clarify sample preparation in analytical testing method of assay.	Take NLT 20 Tablets weigh them crush them and pick weight equivalent to 50mg in a 100ml volumetric flask and add sufficient quantity of diluent to dissolve the powder. Shake for 30min and dilute with diluent to volume. Pass the sample through a syringe tip filer of 0.45 µg pore size The concentration of the above sample is 0.5mg/ml
16.	3.2.P.5.3	Standard and sample preparation in Analytical testing method are different than submitted in analytical testing method of assay. Calrification is required.	The Final Concentration for both sample and standard preparation is same i.e 0.5mg/5ml Standard Preparation: 50mg/5ml = 0.5mg/ml Sample Preparation: 50mg/5ml = 0.5mg/ml
17.	3.2.P.8	• Submit legible commercial invoice attested by DRAP	• Commercial Invoice attested by DRAP is attached.

		• Reference of previous approval of applications with stability study data of the firm	• Reference of previous approval of applications with stability study data of the firm is submitted.

Decision: Approved with Innovator specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

704.	Name, address of Applicant / Marketing Authorization Holder	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd 28-km Ferozepur Road, Lahore – Pakistan
	Name, address of Manufacturing site.	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd 28-km Ferozepur Road, Lahore – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2551: 26-01-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 63858731801
	The proposed proprietary name / brand name	**Obeticol Tablet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Obeticholic Acid.....10 mg
	Pharmacotherapeutic Group of (API)	Bile and liver therapy
	Reference to Finished product specifications	Manufacturer specification
	The status in reference regulatory authorities	OCALIVA 10mg film coated tablets USFDA
	For generic drugs (me-too status)	Obliva 10mg Tablet of M/s Hilton Pharma, Karachi
	Proposed Pack size and Proposed unit price	10's, 20's & 30's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
18.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP inspection report of the manufacturing unit issued within the three years is submitted.
19.	1.5.5	Submit correct Pharmacological group	Obeticholic Acid is a Farnesoid X Receptor Agonist for Primary Biliary Cholangitis.
20.	1.5.6	You have applied Manufacture's specifications so submit following requirements in the light of Guidance Document Regarding Application of Drug Product Specifications: a. Analytical method development and validation report including performance of accuracy, precision, specificity,linearity, ruggedness and robustress parameters as per ICH Q2 (It2) guideline for assay, dissolution and	The Product is of innovator specification and is tested against **Ocaliva Tablets** which is the innovator Product.

		impurities (as applicable),against innovator's product b. The proposed analytical method shall be based upon similar principles (e.g.,chromatographic, spectroscopic, titration) as declared by the innovator drug product literature. c. Comparison between proposed drug product specifications and available innovator's/Reference drug product specifications wherein it could be established that proposed specifications are either equivalent or stringent than the innovator's/ Reference specifications. d. Comparative pharmaceutical equivalence against innovator's/Reference product including comparative dissolution profiling (if applicable). e. Stability study data of the product for accelerated and time period (using stability indicating method) as per the guidelines approved by Registration Board.	
21.	1.6.5 (a)	Two different drug substance manufacturer are submitted in section 1.6.5 and in section 3.2.S.2.1. Clarify from which source drug substance is used for manufacturing of stability batches.	Changzhou Pharmaceutical Factory and Nantong Chanyoo Pharmatech Co., Ltd are the same entities. As Cahngzhou Pharmaceutical Factory owned Nantong Chanyoo Pharmatech Co., Ltd dated 24-07-2014
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Drug Manufacturing License of Nantong Chanyoo Pharmatech Co., Ltd submitted.
22.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided submitted.
23.	3.2.S.4.1	Please justify that why sulphated ash, heavy metals, palladium test ,particle size distribution, solid state form (XRPD), and microbial limits are not included in Drug substance testing specification while same are part of Innovator specifications.	Particle Size distribution and XPRD will be obtained from Drug Substance manufacturer and Sulphated Ash, Heavy metals and Microbial Limits are updated in Analytical method and will be included in commercial Batch. Analytical method of drug substance by drug Product manufacturer is attached**.**
24.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted**.**
25.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted	Analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.

26.	3.2.S.4.4	Provide Certificate of Analysis (CoA) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical ingredient manufacture	Certificate of Analysis (COA) of Drug Substance by Drug Product manufacturer along with Certificate of Analysis (COA) of the same batch from Drug Substance Active Pharmaceutical ingredient manufacturer are submitted.
27.	3.2.S.5	Submitted COA of working standard is from M/s Changzhou Pharmaceutical Factory while details of drug substance submitted from M/s Nantong Chanyoo Pharmatech.	M/s Changzhou Pharmaceutical Factory and M/s Nantong Chanyoo Pharmatech are the same entity; therefore, the provided working Standard COA of the drug substance for the respective batch of API is correct. Statement of Owner ship and Working Standard COA of Drug Substance manufacturer are attached
28.	3.2.S.7	Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	Stability studies at recommended storage conditions of 5°C ± 3°C for drug substance submitted.
29.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document. • Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	• The Pharmaceutical Equivalence study include complete testing of drug product and Reference Product. Pharmaceutical Equivalence report is submitted. • According USFDA Guideline the medium used for Obeticholic Acid Tablets is "0.08% polysorbate 80 in 50mM sodium phosphate dibasic buffer, pH 6.8". and the same is used by drug Product Manufacture. Polysorbate is used by drug product manufacturer in composition of phosphate buffer which is evident from the method of dissolution submitted under 3.2.P.5.1
30.	3.2.P.3.4	Particle size distribution is not conducted by bot drug substance manufacturer and drug product manufacturer and Particle size distribution plays a critical role in the content uniformity and dissolution of the tablets, so what steps has been taken by Drug product manufacturer to confirm the **"**Particle size control**"** of active substance in formulation.	Particle size distribution data will be obtained from the drug substance manufacturer for commercial imports. Furthermore, the dissolution test is an important control for particle size distribution. For commercial batches, we will conduct comparative dissolution tests for control purposes. Additionally, a third-party particle size test can be included for commercial batches
31.	3.2.P.5.1	Please justify that why test for water content and microbial limits form have not been included in stability studies while it is included in innovator product specification	Water Content and Microbial limits has been updated in Analytical method.
32.	3.2.P.5.2	Clarify sample preparation in analytical testing method of assay.	Take NLT 20 Tablets weigh them crush them and pick weight equivalent to 50mg in a 100ml volumetric flask and add

			sufficient quantity of diluent to dissolve the powder. Shake for 30min and dilute with diluent to volume. Pass the sample through a syringe tip filer of 0.45 µg pore size The concentration of the above sample is 0.5mg/ml
33.	3.2.P.5.3	Standard and sample preparation in Analytical testing method are different than submitted in analytical testing method of assay. Calrification is required.	The Final Concentration for both sample and standard preparation is same i.e 0.5mg/5ml Standard Preparation: 50mg/5ml = 0.5mg/ml Sample Preparation: 50mg/5ml = 0.5mg/ml
34.	3.2.P.8	• Submit legible commercial invoice attested by DRAP • Reference of previous approval of applications with stability study data of the firm	• Commercial Invoice attested by DRAP is attached. • Reference of previous approval of applications with stability study data of the firm is submitted.

Decision: Approved with Innovator specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

705.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4044: 13-02-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 5687252832
	The proposed proprietary name / brand name	**Q-Pine 300mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Quetiapine as Quetiapine Fumarate…300mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	SEROQUEL 300mg Tablet of By ASTRAZENECA of USFDA Approved
	For generic drugs (me-too status)	Pine Tablet 300mg of M/s Werrick Pharmaceuticals
	Proposed Pack size and Proposed unit price	1 x 10's & 3 x 10's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply

1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Firm has submitted copy of GMP certificate dated 08-11-2023 based on inspection conducted on 13-10-2023 & 07-11-2023
2.	2.3.R.1.1	Justify Dispensed quantity of Quetiapine with theoretical factor of fumarate	Calculations of dispensing are as follows. 883.1 is molecular weight of Quetiapine Fumarate. 767 is molecular weight of Quetiapine. 883.1/767 = 1.151 So Factor will be 1.151. For a tablet of 300 mg of Quetiapine Fumarate, following quantity 300 x 1.151 = 345.3 mg 345.3 mg of Quetiapine Fumarate is equivalent to 300mg of Quetiapine.
3.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import).	Documents for the procurement of API with approval from DRAP

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

706.	Name, address of Applicant / Marketing Authorization Holder	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi.
	Name, address of Manufacturing site.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36121: 12-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 63858731801
	The proposed proprietary name / brand name	**Tracin 0.3% Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Tobramycin…….3mg
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	The status in reference regulatory authorities	TOBREX (Ophthalmic solution/drops) of USFDA Approved)
	For generic drugs (me-too status)	Tobrex Eye Drop manufactured by Novartis. Reg#097352
	Proposed Pack size and Proposed unit price	1 x 5ml As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.5.5	Submit correct Pharmacological group

2.	1.5.6	Mention the reference specifications of the finished product (drug product) applied.
3.	1.6.5 (a)	Name and address of API manufacturer not mentioned in this section.
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
4.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
5.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
6.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
7.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
8.	3.2.S.4.4	• As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile. • COA of drug substance by drug product manufacturer specifies result of assay in percentage (%) while USP monograph specifies NLT 900 µg/mg of tobramycin on the anhydrous basis. Clarify. • Submit COA of drug substance of the same batch used during product development and stability studies from Drug Substance / /Active Pharmaceutical Ingredient manufacture.
9.	3.2.S.7	Submit Real time stability studies of 3 batches till shelf life as submitted stability studies are till 9 months only.
10.	3.2.P.1	• Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted. • Justification should be submitted for using overage without scientific justification.
11.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
12.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia shall be provided
13.	3.2.P.5.2	• Justify submitted formula for assay calculation with respect to USP monograph. • Analytical testing method for Sterility not submitted.
14.	3.2.P.5.3	• Your sample preparation in Analytical method verification parameter Accuracy and Precision (Repeatability) are different than submitted in analytical testing method of assay as well as USP monograph. Clarification is required. • In Analytical method verification parameter, specificity chromatograms are not submitted.
15.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • How initial testing of all the 03 stability batches have same result of assay. Clarification is required. • How initial testing results in stability summary sheets of Accelerated and Real time stability studies are different. • Sterility testing is not part of stability studies. Clarify.

		• In stability studies raw data calculation are different from applied analytical testing method as well as USP monograph.(Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

707.	Name, address of Applicant / Marketing Authorization Holder	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi.
	Name, address of Manufacturing site.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2385: 25-01-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 59318759401
	The proposed proprietary name / brand name	**Tracin-D Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Tobramycin……3mg Dexamethasone…….1mg
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	The status in reference regulatory authorities	TobraDex ophthalmic suspension by Novartis Pharmaceuticals of (USFDA Approved)
	For generic drugs (me-too status)	TobraDex Eye Drop by NOVARTIS Pharmaceutical
	Proposed Pack size and Proposed unit price	1 x 5ml As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.3.5	Evidence of separate dispensing booths for steroids.
2.	1.5.5	Submit correct Pharmacological group
3.	1.5.6	Mention the reference specifications of the finished product (drug product)
4.	1.6.5 (a)	Name and address of both API manufacturer not mentioned in this section.
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for both Tobramycin and Dexamethasone.
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
		Tobramycin
6.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
7.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.

8.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
9.	3.2.S.4.4	• As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile. • COA of drug substance by drug product manufacturer specifies result of assay in percentage (%) while USP monograph specifies NLT 900 µg/mg of tobramycin on the anhydrous basis. Clarify. • Submit COA of drug substance of the same batch used during product development and stability studies from Drug Substance / /Active Pharmaceutical Ingredient manufacture.
10.	3.2.S.7	Submit Real time stability studies of 3 batches till shelf life submitted till 9 months only.
Dexamethasone		
11.	3.2.S.4.1	• Submitted specification by drug substance manufacturer are of Dexamethasone Sodium Phosphate while in applied product Dexamethasone is used. Clarification is required. • Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required
12.	3.2.S.4.2	• Submitted analytical procedures by drug substance manufacturer are of Dexamethasone Sodium Phosphate while in applied product Dexamethasone is used. Clarification is required • Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
13.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
14.	3.2.S.4.4	Submitted COA of drug substance by drug substance manufacturer and drug product manufacturer are of Dexamethasone Sodium Phosphate while as per USP monograph and Innovator product Dexamethasone is used. Clarification is required.
15.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.
16.	3.2.S.7	Submit Accelerated and Real time stability studies of 3 batches for Dexamethasone.
Product		
17.	3.2.P.1	• You have applied for ophthalmic solution while the applied product is approved as ophthalmic suspension in USFDA. Correct the applied formulation along with submission of full fee of registration. • Justification should be submitted for using overage without scientific justification.
18.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
19.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia shall be provided
20.	3.2.P.5.2	• Justify submitted formula of Tobramycin for assay calculation with respect to USP monograph. • Analytical testing method for Sterility not submitted.
21.	3.2.P.5.3	• Your sample preparation in Analytical method verification parameter Accuracy and Precision (Repeatability) are different than submitted in analytical testing method of assay as well as USP monograph. Clarification is required.

		• In Analytical method verification parameter, specificity chromatograms are not submitted.
22.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • Sterility testing is not part of stability studies. Clarify. • In stability studies raw data calculation are different from applied analytical testing method as well as USP monograph • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

708.	Name, address of Applicant / Marketing Authorization Holder	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Name, address of Manufacturing site.	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2547: 26-01-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 32238158201
	The proposed proprietary name / brand name	**Rostril 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Racecadotril (BP)…….100mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Reference to Finished product specifications	In-house
	The status in reference regulatory authorities	Hidrasec® Capsules 100mg by Sophartex of France Approved.
	For generic drugs (me-too status)	"Hidrasec® Capsules 100mg" by M/s Abbott Laboratories Reg# 087518
	Proposed Pack size and Proposed unit price	10's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.5.3	Approval letter of the section (Dosage form) in which manufacturing of the applied product is to be carried out needs to be submitted
2.	1.5.6	You have applied Manufacture's specifications so submit following requirements in the light of Guidance Document Regarding Application of Drug Product Specifications: a. Analytical method development and validation report including performance of accuracy, precision, specificity, linearity, ruggedness and robustness parameters as per ICH Q2 (It2) guideline for assay, dissolution and impurities (as applicable),against innovator's product b. The proposed analytical method shall be based upon similar principles (e.g.,chromatographic, spectroscopic, titration) as declared by the innovator drug product literature. c. Comparison between proposed drug product specifications and available

		innovator's/Reference drug product specifications wherein it could be established that proposed specifications are either equivalent or stringent than the innovator's/ Reference specifications. d. Comparative pharmaceutical equivalence against innovator's/Reference product including comparative dissolution profiling (if applicable). e. Stability study data of the product for accelerated and time period (using stability indicating method) as per the guidelines approved by Registration Board.
3.	1.6.5 (a)	Address of API manufacturer site is different than mentioned in GMP and COA of drug substance..
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
4.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
5.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
7.	3.2.P.2.2.1	Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while as per innovator drug product literature active ingredient is insoluble throughout the physiological range and that a surfactant will increase the drug substance solubility.
8.	3.2.P.5.1	Please justify that why test for water content and microbial limits have not been included in stability studies while it is included in innovator product specification
9.	3.2.P.5.2	• Reference shall be submitted for the dissolution parameters adopted. • You have not mentioned which dissolution medium is used. • You have applied Paddle speed = 100 rpm in dissolution parameters. You are advised to justify the speed of paddle apparatus with reference to USP general chapter <1092> (The Dissolution Procedure; Development and Validation).
10.	3.2.P.5.3	• Your sample preparation in Analytical method verification parameter Accuracy and Precision (Repeatability) are different than submitted in analytical testing method of assay . Clarification is required. • In analytical method verification concentration is mentioned in µg.ml while preparation solution shows mg/ml. • In Analytical method verification parameter, specificity chromatograms are not submitted.
11.	3.2.P.5.4	In COA's of stability batches BP specifications are mentioned while product is not available in BP pharmacopeia. Clarification is required.
12.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • Initiation date of stability studies not mentioned. • In stability studies raw data sample preparation is different from applied analytical testing method of assay.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

709.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36818: 19-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 3181685383
	The proposed proprietary name / brand name	**Dotril 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Racecadotril (BP)…….100mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Reference to Finished product specifications	Innovator specification.
	The status in reference regulatory authorities	Racecadotril Capsules 100mg by Biogran of France Approved.
	For generic drugs (me-too status)	"Hidrasec® Capsules 100mg" by M/s Abbott Laboratories Reg# 087518
	Proposed Pack size and Proposed unit price	10's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.2	Ph.Eur Specfications are applied on drug substance than how limits of assay are 90- 110% by drug product manufacturer
3.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
4.	3.2.S.7	Submit Real time stability studies for 3 batches till shelf life as submitted stability studies are of 12 months.
5.	3.2.P.5.1	• Justification is required for Performance of LOD instead of Water content as Innovator includes water content test. • You have mentioned dissolution specification NLT 80% (Q) in section 3.2.P.5.1 while in rest of documents mentioned as NLT 75% (Q). Clarification is required.
6.	3.2.P.5.2	• Reference shall be submitted for the dissolution parameters adopted. • You have applied Paddle speed = 100 rpm in dissolution parameters. You are advised to justify the speed of paddle apparatus with reference to USP general chapter <1092> (The Dissolution Procedure; Development and Validation).
7.	3.2.P.5.3	• Your sample preparation in Analytical method verification parameter are different than submitted in analytical testing method of assay . Clarification is required.
8.	3.2.P.5.4	In COA's of stability batches BP specifications are mentioned while product is not available in BP pharmacopeia. Clarification is required.
9.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • Initiation date of stability studies not mentioned. • In Stability studies summary sheets batch No mentioned and Batch No BMR's rest of documents Batch No are different. Clarification is required. • In stability studies raw data sample preparation is different from applied analytical testing method of assay • In submitted raw data of dissolution Type I Apparatus is used while in analytical testing method of dissolution Type 2 Apparatus is mentioned. Clarification is required.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

b. Deferred cases

710.	Name, address of Applicant / Marketing Authorization Holder	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Sapient: Firm has submitted copy of GMP certificate dated 22-04-2020 based on inspection conducted on 18-11-2019 and valid until for 2 years Bio Mark Pharmaceuticals: Firm has submitted copy of GMP certificate dated 22-04-2020 based on inspection conducted on 13-02-2020 and valid until for one years
	Evidence of approval of manufacturing facility	Firm has submitted copy cGMP certificate (Bio Mark Pharmaceuticals specifying Tablet I and Tablet II (General)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25074 dated 05-09-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 182968739
	The proposed proprietary name / brand name	Rosicar 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin (as Calcium)…10mg
	Pharmacotherapeutic Group of (API)	Statins (lipid lowering drug)
	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CRESTOR of (USFDA Approved)
	For generic drugs (me-too status)	Rolip 10mg Tablet of M/s Hilton pharma.
	Name and address of API manufacturer.	M/s Morpean Laboratoies Limited Village Malkumajra (Morepen Village), Baddi Nalagarh Road.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months Batches: (RT-12-KL-0001, RT-12-KL-0002 & RT-12-KL-0003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the CRESTOR 10mg Tablet by AstraZeneca performing quality tests (Identification, Description, Uniformity of dosage units, Assay, and Dissolution). CDP has been performed against the 'CRESTOR 10mg Tablet by AstraZeneca , in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	

STABILITY STUDY DATA	
Manufacturer of API	M/s Morpean Laboratoies Limited Village Malkumajra (Morepen Village), Baddi Nalagarh Road.
API Lot No.	RTC 9012
Description of Pack (Container closure system)	Alu-Alu
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	20K333	21A216	21K393
Batch Size	8000 Tablet	100000 Tablet	50000 Tablet
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 173205 issued by Health & family welfare Department Himachel Pradesh issued on 10/11/2022 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice # MBE20181900596 dated: 26-02-2019 not attested by DRAP specifying 05Kg of Rosuvastatin Calcium batch # RTC 9012
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming
1.	1.4.3	Provide notarized copy of Contract manufacturing agreement
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.2	In standard and sample preparation USP specify diluent : Acetonitrile and water (25:75) while you are using Acetonitrile and water separately. Justify.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer instead of drug substance manufacture for drug substance(s) shall be submitted.
5.	3.2.S.4.4	• Enantiomeric Purity is not performed as mentioned in USP monograph. Justify. • COA of drug substance by drug product manufacturer is not signed.
6.	3.2.P.5.2	You have not mentioned which dissolution method was adopted from USP monograph.
7.	3.2.P.5.3	Submit analytical method verification of drug product instead of drug substance.
8.	3.2.P.5.4	The copies of complete analysis of stability batches shall be provided.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-331): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.4.3	Provide notarized copy of Contract manufacturing agreement	Copy of Contract manufacturing agreement submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 submitted.
3.	3.2.S.4.2	In standard and sample preparation USP specify diluent : Acetonitrile and water (25:75) while you are using Acetonitrile and water separately. Justify.	Dilutions are prepared in accordance to USP monograph for Rosuvastatin tablet , wherein the ultimate concentration of diluent in preparing standard stock solution & sample solution remains as that stated in diluent premixed value i. e Acctonitrile 25: water 75.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer instead of drug substance manufacture for drug substance(s) shall be submitted.	Analytical method verification studies are submitted.
5.	3.2.S.4.4	• Enantiomeric Purity is not performed as mentioned in USP monograph. Justify. • COA of drug substance by drug product manufacturer is not signed.	• Not submitted**.** • COA of drug substance by drug product manufacturer signed copy submitted.
6.	3.2.P.5.2	You have not mentioned which dissolution method was adopted from USP monograph.	Dissolution Test 3 method is adopted from USP monograph for Rosuvastatin tablet.
7.	3.2.P.5.3	Submit analytical method verification of drug product instead of drug substance.	Submitted
8.	3.2.P.5.4	The copies of complete analysis of stability batches shall be provided.	Copies of complete analysis of stability batches submitted.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• Documents for the procurement of API with approval from DRAP submitted. • HPLC system used for the analysis of Rosuvastatin tablet was not 21CFR Compliant.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s PDH Laboratories Pvt Ltd. **(New Section)** CLB in its 285th meeting held on 17th & 18th March 2022, has approved the following 01 additional sections of M/s PDH Laboratories Pvt Ltd. 1.Oral liquid Section (General) Additional		
711.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3222 dated 03-02-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 708047908
	The proposed proprietary name / brand name	Temol Suspension 120mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….120mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 120 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol Pediatric Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability

		studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.		
API Lot No.	21GN60187		
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of a leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-006	T-007	T-008
Batch Size	40 bottles	40 bottles	40 bottles

Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	10-12-2021	10-12-2021	10-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.2	In Assay final concentrations is 0.01mg/ml while 96 mg of paracetamol from oral suspension taken. Clarify how from 96mg 0.01mg/ml concentration prepared.
4.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
5.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-327): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while	The revised precision parameter of analytical method verification of drug substance is attached.

		you have used 6 determinations (3 concentrations /2 replicates each).	
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.	The testing of reference product was performed as per claimed product specifications (BP Specs). Temol suspension was built on USP specifications during the product development phase. However revised pharmaceutical equivalence according USP specifications is submitted.
3.	3.2.P.5.2	In Assay final concentrations is 0.01mg/ml while 96 mg of paracetamol from oral suspension taken. Clarify how from 96mg 0.01mg/ml concentration prepared.	It was typo error .The revised analytical method is submitted. 100mg of paracetamol from oral suspension taken.
4.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	The revised precision parameter of analytical method verification of drug product is submitted.
5.	3.2.P.8	• Purchase Documents for Paracetamol. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• The API was locally purchased. Purchased documents of paracetamol are attached.(Invoice #PRT/2021/0185 dated: 29-07-2021) • Compliance record of HPLC software 21 CFR & audit trail reports on product testing

Previous Decision (M-330): Deferred for following clarifications:

- Manufacturing facility along with details of equipment's wherein the trial batches have been manufactured along with evidence of approval of required manufacturing facility from CLB.
- Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.

- Equipment list along with Syrup Section approval from CLB submitted.
- Firm submitted stability data of 03 new batches.

Batch No.	T-10	T-11	T-12
Batch Size	10 Liters	10 Liters	10 Liters
Manufacturing Date	January 2023	January 2023	January 2023
Date of Initiation	07-01-2023	07-01-2023	07-01-2023

Evaluation by PEC:

- Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following
  "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.

- 330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.
- Details of equipment's along with their capacity wherein new trial batches have been Manufactured.
- Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided.
- Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Reason of deferment	Reply
1.	Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.	It is submitted that, Earlier, trials of the product were manufactured with batch size 2.40 Liters in November 2021 and stability studies were submitted in the dossiers accordingly. Afterwards, we have manufactured new trials with Batch size 10 Liters to re-assure the compliance and stability. Hence, we have submitted the data for newly manufactured batches for consideration. In both cases, out product found to be stable.
2.	330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.	The dossier was under evaluation since February 2023, and we have submitted the 12 months' real-time stability study data with the dossier. The new trials were manufactured in January 2023 and six months' accelerated stability study was completed in July 2023. As per DRAP CTD guidelines, six months' accelerated stability study data is required for evaluation, so before that we could not submit the stability data of newly manufactured batches.
3.	Details of equipment's along with their capacity wherein new trial batches have been Manufactured.	Equipment list submitted Mixing tank of 150L Capacity used. Firm submitted Calibration certificate which shows capacity from 10L to 150L and also submitted Performance qualification protocol and report for 150L mixing tank with working Range from 10L to 100L.
4.	Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided	Details of drug substance and copy of Batch Manufacturing Record (BMR) are attached
5.	Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

712.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan

	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7379 dated 14-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3924666116
	The proposed proprietary name / brand name	Temol DS Suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….250mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 250 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol 6 plus Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for

		impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol 6 Plus Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.		
API Lot No.	21GN60187		
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of a leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-007	T-008	T-009
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	20-06-2022	22-06-2022	24-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
4.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-327): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	The revised precision parameter of analytical method verification of drug substance is attached.
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.	The testing of reference product was performed as per claimed product specifications (BP Specs). Temol suspension was built on USP specifications during the product development phase. However revised pharmaceutical

			equivalence according USP specifications is submitted.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	The revised precision parameter of analytical method verification of drug product is submitted.
4.	3.2.P.8	• Purchase Documents for Paracetamol. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• The API was locally purchased. Purchased documents of paracetamol are attached.(Invoice #PRT/2021/0185 dated: 29-07-2021) • Compliance record of HPLC software 21 CFR & audit trail reports on product testing

Previous Decision (M-330): Deferred for following clarifications:

- Manufacturing facility along with details of equipment's wherein the trial batches have been manufactured along with evidence of approval of required manufacturing facility from CLB.
- Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.

- Equipment list along with Syrup Section approval from CLB submitted.
- Firm submitted stability data of 03 new batches.

Batch No.	T-11	T-12	T-13
Batch Size	10 Liters	10 Liters	10 Liters
Manufacturing Date	January 2023	January 2023	January 2023
Date of Initiation	14-01-2023	14-01-2023	14-01-2023

Evaluation by PEC:

- Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following
- "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.
- 330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.
- Details of equipment's along with their capacity wherein new trial batches have been
- Manufactured.
- Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided.
- Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Reason of deferment	Reply

1.	Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.	It is submitted that, Earlier, trials of the product were manufactured with batch size 2.40 Liters in November 2021 and stability studies were submitted in the dossiers accordingly. Afterwards, we have manufactured new trials with Batch size 10 Liters to re-assure the compliance and stability. Hence, we have submitted the data for newly manufactured batches for consideration. In both cases, out product found to be stable.
2.	330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.	The dossier was under evaluation since February 2023, and we have submitted the 12 months' real-time stability study data with the dossier. The new trials were manufactured in January 2023 and six months' accelerated stability study was completed in July 2023. As per DRAP CTD guidelines, six months' accelerated stability study data is required for evaluation, so before that we could not submit the stability data of newly manufactured batches.
3.	Details of equipment's along with their capacity wherein new trial batches have been Manufactured.	Equipment list submitted Mixing tank of 150L Capacity used. Firm submitted Calibration certificate which shows capacity from 10L to 150L and also submitted Performance qualification protocol and report for 150L mixing tank with working Range from 10L to 100L.
4.	Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided	Details of drug substance and copy of Batch Manufacturing Record (BMR) are attached
5.	Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Medevo (Private) Ltd. . **(New DML)**
CLB in its 288th meeting held on 18th October 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s Medevo (Private) Ltd.

1) Eye Drops (General)
2) Eye Ointment (General)

Eye Drops (General)		
713.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23152 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 10783694194
	The proposed proprietary name / brand name	Surgilot Eye Drops (0.5% Ophthalmic Suspension)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Loteprednol Etabonate……5mg
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LOTEMAX ophthalmic suspension/drops; of USFDA Approved
	For generic drugs (me-too status)	Lotepred forte Ophthalmic suspension of M/s of Sante private limited Reg# 0674458
	Name and address of API manufacturer.	M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lotepred Forte of M/s Sante Pharmaceuticals by performing quality tests Identification, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.		
API Lot No.	LOT/MS/22/009		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LOTF-Trial001	LOTF-Trial002	LOTF-Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	03-12-2022	03-12-2022	03-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Drugs import License # K-987059032758, dated; 29-09-2022 specifying Loteprednol Etabonate.(Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
2.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
4.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
6.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
7.	3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.
8.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copies of the Drug substance specifications by Drug Product manufacturer submitted.
2.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer submitted.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer submitted.
4.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.	HCl solution is used to adjust the pH and evident from batch manufacturing record.
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies submitted.
6.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	Analytical method validation protocol and report are submitted.

7.	3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.	Certificate of analysis of 3 batches submitted.
8.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• As per ICH an alternative approach to study at the reference relative humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below

Alternative relative humidity	Reference relative humidity	Ratio of water loss rates at a given temperature
65% RH	35% RH	1.9
75% RH	25% RH	3.0

And our water loss is less than 5% from initial value.

- Water loss test for 6th months submitted.
- Complete raw data of stability studies submitted.
- Compliance Record of HPLC software submitted.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

714.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23156 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 929420703
	The proposed proprietary name / brand name	Surgilot-T 0.5/0.3% Opthalmic Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Loteprednol Etabonate……5mg Tobramycin……3mg
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZYLET ophthalmic suspension/drops; of USFDA Approved
	For generic drugs (me-too status)	Lotepred-T Ophthalmic suspension of M/s of Sante private limited Reg# 070515
	Name and address of API manufacturer.	**Loteprednol Etabonate:** M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India. **Tobramycin:** Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Loteprednol Etabonate**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for

		6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lotepred-T of M/s Sante Pharmaceuticals by performing quality tests Identification, Clarity, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	**Loteprednol Etabonate**: Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India. **Tobramycin:** Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	**Loteprednol Etabonate:**LOT/MS/22/009 **Tobramycin:** 08210702-U		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LOTT-Trial001	LOTT-Trial002	LOTT-Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	14-12-2022	14-12-2022	14-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Loteprednol Etabonate:** Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024 **Tobramycin:** Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Loteprednol Etabonate:** An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Drugs import License # K-987059032758, dated; 29-09-2022 specifying Loteprednol Etabonate.(Innovotek pharmaceuticals) **Tobramycin:** An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifying Tobramycin base Batch #.08210702-U (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.5	Complete Pharmacological group is not mentioned
2.	1.6.5	Submitted GMP certificate for drug substance (Tobramycin) could not be verified from NMPA site. Clarify.
3.	3.2.S.4.1	Copies of the Drug substance (Loteprednol Etabonate) specifications by Drug Product manufacturer is required.
4.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Loteprednol Etabonate) by Drug Product manufacturer is required.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) (Loteprednol Etabonate & Tobramycin)shall be submitted.
6.	3.2.S.7	Submit stability studies of drug substance (Tobramycin) as per zone IV-A/B
7.	3.2.P.1	Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
8.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
9.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.5.5	Complete Pharmacological group is not mentioned	Complete pharmacological group submitted as Corticosteroid and Antibiotic

<table>
<tr><td>2.</td><td>1.6.5</td><td>Submitted GMP certificate for drug substance (Tobramycin) could not be verified from NMPA site. Clarify.</td><td>Copy of DML# Chongqing 20150039 issued by NMPA dated: 22-12-2022 and valid till 15-11-2025 submitted.</td></tr>
<tr><td>3.</td><td>3.2.S.4.1</td><td>Copies of the Drug substance (Loteprednol Etabonate) specifications by Drug Product manufacturer is required.</td><td>Copies of the Drug substance (Loteprednol Etabonate) specifications by Drug Product manufacturer) submitted</td></tr>
<tr><td>4.</td><td>3.2.S.4.2</td><td>Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Loteprednol Etabonate) by Drug Product manufacturer is required.</td><td>Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Loteprednol Etabonate) by Drug Product manufacturer) submitted</td></tr>
<tr><td>5.</td><td>3.2.S.4.3</td><td>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) (Loteprednol Etabonate & Tobramycin)shall be submitted.</td><td>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer submitted</td></tr>
<tr><td>6.</td><td>3.2.S.7</td><td>Submit stability studies of drug substance (Tobramycin) as per zone IV-A/B</td><td>Stability studies of drug substance as per zone IV-A submitted</td></tr>
<tr><td>7.</td><td>3.2.P.1</td><td>Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.</td><td>Sodium hydroxide is used to adjust the pH and evident from batch manufacturing record.</td></tr>
<tr><td>8.</td><td>3.2.P.2.5</td><td>Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.</td><td>Preservative effectiveness studies submitted</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method validation protocol and report for drug product shall be performed.</td><td>Analytical method validation protocol and report are submitted</td></tr>
<tr><td>10.</td><td>3.2.P.8</td><td>• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines.
• Water loss test submitted for only 3 months. Clarify.
• Submit complete raw data of stability studies.
• Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• As per ICH an alternative approach to study at the reference relative humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below
<table>
<tr><th>Alternative relative humidity</th><th>Reference relative humidity</th><th>Ratio of water loss rates at a given temperature</th></tr>
<tr><td>65% RH</td><td>35% RH</td><td>1.9</td></tr>
<tr><td>75% RH</td><td>25% RH</td><td>3.0</td></tr>
</table>
And our water loss is less than 5% from initial value.
• Water loss test for 6th months submitted</td></tr>
</table>

			• Complete raw data of stability studies submitted • Compliance Record of HPLC software submitted

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

715.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 26021 dated 27-10-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 31222688015
	The proposed proprietary name / brand name	Surgitob 0.3% Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Tobramycin …….3mg
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TOBREX (Ophthalmic solution/drops) of USFDA Approved
	For generic drugs (me-too status)	Tobrex Eye Drop manufactured by Novartis. Reg#097352
	Name and address of API manufacturer.	M/s Chongqing Daxin Pharmaceuticals Co.Ltd. BeiBei, ChongQing people Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tobrex Eye Drops manufactured by Alcon by performing quality tests Identification, Description/Appearance, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	08191203-U		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TMD-Trial001	TMD -Trial002	TMD -Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	30-11-2022	30-11-2022	30-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifying Tobramycin base Batch #.08191203-U (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
5.	3.2.S.7	Submit stability studies of drug substance as per zone IV-A/B
6.	3.2.P.1	Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
7.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
8.	3.2.P.5.2	Detailed analytical procedures used for testing the drug product shall be provided.
9.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division**.**

S.No	Section	Shortcoming	Reply
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.	Copy of DML# Chongqing 20150039 issued by NMPA dated: 22-12-2022 and valid till 15-11-2025 submitted.

<table>
<tr><td>2.</td><td>3.2.S.4.1</td><td>Copies of the Drug substance specifications by Drug Product manufacturer is required.</td><td>Copies of the Drug substance specifications by Drug Product manufacturer are submitted.</td></tr>
<tr><td>3.</td><td>3.2.S.4.2</td><td>Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.</td><td>Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted.</td></tr>
<tr><td>4.</td><td>3.2.S.4.3</td><td>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.</td><td>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer submitted.</td></tr>
<tr><td>5.</td><td>3.2.S.7</td><td>Submit stability studies of drug substance as per zone IV-A/B</td><td>Stability studies of drug substance as per zone IV-A submitted.</td></tr>
<tr><td>6.</td><td>3.2.P.1</td><td>Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.</td><td>Sodium hydroxide is used to adjust the pH and evident from batch manufacturing record.</td></tr>
<tr><td>7.</td><td>3.2.P.2.5</td><td>Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.</td><td>Preservative effectiveness studies submitted.</td></tr>
<tr><td>8.</td><td>3.2.P.5.2</td><td>Detailed analytical procedures used for testing the drug product shall be provided.</td><td>Analytical procedures used for testing the drug product submitted.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method validation protocol and report for drug product shall be performed.</td><td>Analytical method validation protocol and report are submitted.</td></tr>
<tr><td>10.</td><td>3.2.P.8</td><td>• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines.
• Water loss test submitted for only 3 months. Clarify.
• Submit complete raw data of stability studies.
• Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• As per ICH an alternative approach to study at the reference relative humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below
<table>
<tr><th>Alternative relative humidity</th><th>Reference relative humidity</th><th>Ratio of water loss rates at a given temperature</th></tr>
<tr><td>65% RH</td><td>35% RH</td><td>1.9</td></tr>
<tr><td>75% RH</td><td>25% RH</td><td>3.0</td></tr>
</table>
And our water loss is less than 5% from initial value.
• Water loss test for 6th months submitted.
• Complete raw data of stability studies submitted.</td></tr>
</table>

			• Compliance Record of HPLC software submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

716.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23155 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 9658797258
	The proposed proprietary name / brand name	**Surgimox Eye Drop (0.5% ophthalmic Solution)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Moxifloxacin Hcl eq. to Moxifloxacin…….5mg
	Pharmaceutical form of applied drug	Antibiotic
	Pharmacotherapeutic Group of (API)	Clear yellowish solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VIGAMOX (USFDA Approved)
	For generic drugs (me-too status)	Vigamox Eye Drop of by Novartis Pharma Reg # 093920.
	Name and address of API manufacturer.	M/s Zheijiang Guobang Pharmaceuticals Co., Ltd. No. 6 Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of **2** batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Vigamox Eye Drop manufactured by Alcon Laboratories. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	M/s Zheijiang Guobang Pharmaceuticals Co., Ltd. No. 6 Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.		
API Lot No.	E109-220312-1		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MOXE Trial 001	MOXE Trial 002	MOXE Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	23-11-2022	23-11-2022	23-11-2022

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML certificate (No. Zhejiang 20050288) issued by NMPA, dated 17-01-2024 and valid till 08-12-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Biorex pharmaceuticals submitted. Firm has submitted copy of Form 5 (Drug Import License, dated; 11-08-2020 specifying Moxifloxacin HCL (Biorex pharmaceuticals) Firm has submitted copy of Clearance certificate # specifying Invoice #GBP2022-0973, dated; 21-07-2020 specifying Moxifloxacin HCL Batch #. E109-220312-1 issued on 31-08-2022(Biorex pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance for 3 batches
6.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
7.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of DML certificate (No. Zhejiang 20050288) issued by NMPA, dated 17-01-2024 and valid till 08-12-2024
2.	3.2.S.4.1	Copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications by Drug Product manufacturer are submitted.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer submitted.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance for 3 batches	Stability studies of drug substance as per zone IV-A of 3 batches submitted.
6.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.	Hydrochloric acid is used to adjust the pH and evident from batch manufacturing record.
7.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies submitted.
8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	Analytical method verification protocol and report are submitted.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	Certificate of analysis of working standard submitted.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• As per ICH an alternative approach to study at the reference relative humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below

Alternative relative humidity	Reference relative humidity	Ratio of water loss rates at a given

			<table><tr><td></td><td></td><td>temperature</td></tr><tr><td>65% RH</td><td>35% RH</td><td>1.9</td></tr><tr><td>75% RH</td><td>25% RH</td><td>3.0</td></tr></table> And our water loss is less than 5% from initial value. • Water loss test for 6th months submitted. • Complete raw data of stability studies submitted. • Compliance Record of HPLC software submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

717.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23154 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 087533119
	The proposed proprietary name / brand name	**Surgipat DS Eye Drop (0.2% Ophthalmic Solution)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Olopatadine Hcl eq. to Olopatadine…….2mg
	Pharmaceutical form of applied drug	Antiallergics
	Pharmacotherapeutic Group of (API)	Ophthalmic Clear solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PATADAY (USFDA Approved)
	For generic drugs (me-too status)	Olotek-DS Eye Drop manufactured by Innovotek Pharmaceuticals.

	Name and address of API manufacturer.	M/s Precise chemipharma private limited India. Address: C-384 TTC Industrial Area MiDC, Pawane Village, Navi Mumbai, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Olotek-DS Eye Drop manufactured by Innovotek Pharmaceuticals. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA	
Manufacturer of API	M/s Precise chemipharma private limited India. Address: C-384 TTC Industrial Area MiDC, Pawane Village, Navi Mumbai, India.
API Lot No.	055008062020
Description of Pack (Container closure system)	LDPE bottle
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OLP Trial 001	OLP Trial 002	OLP Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	25-11-2022	25-11-2022	25-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6109110) issued by Food & Adminstration Maharashtra state India, (for Precise Biopharma Pvt Ltd) dated 19-09-2022 and valid till 15-09-2023 (Firm submitted Decleration from drug substance manufacturer that their company name change from Precise chemipharm Pvt Ltd to Precise Biopharma pvt Ltd.)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of form 5 and Clearance certificate specifying Invoice #EXPI/00055/20-21, dated; 08-07-2020 specifying Olopatadine Hcl Batch #.055008062020 (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
3.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
4.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
5.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
6.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
7.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines.

		• Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of GMP certificate (No. 6115332) issued by Food & Adminstration Maharashtra state India, (for Precise Biopharma Pvt Ltd) dated 20-09-2023 and valid till 19-09-2024
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer submitted.
3.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.	Hydrochloric acid is used to adjust the pH and evident from batch manufacturing record.
4.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies submitted.
5.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	Analytical method verification protocol and report are submitted.
6.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	Certificate of analysis of working standard submitted.
7.	3.2.P.8	• Stability studies are conducted at Real time : 30°C ± 2°C / 65% ± 5%RH and Accelerated: 40°C ± 2°C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• As per ICH an alternative approach to study at the reference relative humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below

Alternative relative humidity	Reference relative humidity	Ratio of water loss rates at a given temperature
65% RH	35% RH	1.9
75% RH	25% RH	3.0

And our water loss is less than 5% from initial value.

			• Water loss test for 6th months submitted. • Complete raw data of stability studies submitted. • Compliance Record of HPLC software submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

718.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23153 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 087952225
	The proposed proprietary name / brand name	**Surgidor-T Eye Drop**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dorzolamide Hcl eq. to Dorzolamide…….20mg Timolol Maleate eq. to Timolol …….5mg
	Pharmaceutical form of applied drug	Anti-glaucoma
	Pharmacotherapeutic Group of (API)	Ophthalmic Clear solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COSOPT (USFDA Approved)
	For generic drugs (me-too status)	Cosopt Eye Drop manufactured by OBS Pakistan Reg# 025294
	Name and address of API manufacturer.	**Dorzolamide Hcl & Timolol Maleate**:M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Dorzolamide Hcl:** Firm has submitted stability study data of 2 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Timolol Maleate:** Firm has submitted stability study data of 2 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Cosopt Eye Drop manufactured by SANTEN Pharmaceuticals Co, Ltd.. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA	
Manufacturer of API	**Dorzolamide Hcl & Timolol Maleate:**M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.
API Lot No.	**Dorzolamide Hcl:** DOR/21/002 **Timolol Maleate:** TIM/21/001
Description of Pack (Container closure system)	LDPE bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DRTI Trial 001	DRTI Trial 002	DRTI Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	27-11-2022	27-11-2022	27-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dorzolamide Hcl & Timolol Maleate:**Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of form 5 and Clearance certificate specifying Invoice #FLX/EX/00055/20-21/036, dated; 15-03-2021 specifying Dorzolamide Hcl Batch #. DOR/21/002 & Timolol Maleate Batch # TIM/21/001 (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance (Dorzolamide Hcl & Timolol Maleate)specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Dorzolamide Hcl & Timolol Maleate)Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) Dorzolamide Hcl & Timolol Maleate shall be submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance (Dorzolamide Hcl & Timolol Maleate) for 3 batches.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
7.	3.2.P.5.2	Standard and sample concentrations of Dorzolamide Hcl are different from USP monograph

8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division**.**

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024
2.	3.2.S.4.1	Copies of the Drug substance (Dorzolamide Hcl & Timolol Maleate)specifications by Drug Product manufacturer is required.	Copies of the Drug substance (Dorzolamide Hcl & Timolol Maleate)specification are submitted.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Dorzolamide Hcl & Timolol Maleate)Drug Product manufacturer is required.	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Dorzolamide Hcl & Timolol Maleate)Drug Product manufacturer submitted.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) Dorzolamide Hcl & Timolol Maleate shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) Dorzolamide Hcl & Timolol Maleate are submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance (Dorzolamide Hcl & Timolol Maleate) for 3 batches.	Submit Accelerated and long term stability studies of drug substance (Dorzolamide Hcl & Timolol Maleate) for 3 batches submitted.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies submitted.
7.	3.2.P.5.2	Standard and sample concentrations of Dorzolamide Hcl are different from USP monograph	Revised analytical testing method submitted.
8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	Analytical method verification protocol and report submitted.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	Certificate of analysis of working standard submitted.
10.	3.2.P.8	• Stability studies are conducted at Real time :	• As per ICH an alternative approach to study at the reference relative

		30°C ± 2°C / 65% ± 5%RH and Accelerated: 40°C ± 2°C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	humidity (for either long term or accelerated testing) is perform the stability studies under higher relative humidity and derive the water loss rate at the reference relative humidity is to multiply the water loss rate measured at an alternative relative humidity at the same temperature by a water loss rate ratio shown in the table below Alternative relative humidity | Reference relative humidity | Ratio of water loss rates at a given temperature 65% RH | 35% RH | 1.9 75% RH | 25% RH | 3.0 And our water loss is less than 5% from initial value. • Water loss test for 6th months submitted. • Complete raw data of stability studies submitted. • Compliance Record of HPLC software submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Eye Ointment (General)

719.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 26021 dated 22-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 79054979901

	The proposed proprietary name / brand name	Surgitob 0.3% Eye Ointment
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Tobramycin …….3mg
	Pharmaceutical form of applied drug	Off White semi solid ointment
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	3.5gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TOBREX (Ophthalmic ophthalmic ointment) of USFDA Approved)
	For generic drugs (me-too status)	Tobrex Eye Drop manufactured by Novartis. Reg#093921
	Name and address of API manufacturer.	M/s Chongqing Daxin Pharmaceuticals Co.Ltd. BeiBei, ChongQing people Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tobrex Ointment manufactured by M/s Novartis Private Ltd. by performing quality tests Identification, Description/Appearance, Assay, and Sterility Test,).

	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	08210702-U		
Description of Pack (Container closure system)	Collapsible Aluminium Tubes		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TME Trial 001	TME Trial 002	TME Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	14-12-2022	30-11-2022	14-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifying Tobramycin base Batch #.08191203-U (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
3.	3.2.S.4.4	As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile.

4.	3.2.S.7	Submit stability studies of drug substance as per zone IV-A/B
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
6.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
7.	3.2.P.8	• Submit complete raw data of stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Previous Decision (M-333): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division**.**

S.No	Section	Shortcoming	Reply
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.	Copy of DML# Chongqing 20150039 issued by NMPA dated: 22-12-2022 and valid till 15-11-2025 submitted.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance manufacturer are submitted.
3.	3.2.S.4.4	• As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile.	Revised COA submitted.
4.	3.2.S.7	Submit stability studies of drug substance as per zone IV-A/B	Stability studies of drug substance as per zone IV-A Submitted.
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies Submitted.
6.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	Analytical method verification protocol and report Submitted.
7.	3.2.P.8	• Submit complete raw data of stability studies • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Complete raw data of stability studies Submitted. • Compliance Record of HPLC software Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s DS Pharma. **(New DML)**

CLB in its 289th meeting held on 23rd January 2023 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s DS Pharma.

1) Liquid Injectable (SVP) (Ampoule) Section (General)
2) Liquid Injectable (SVP) (Ampoule) Section (Steroid)

720.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma

		Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 16140 dated 26-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 079958644
	The proposed proprietary name / brand name	**Licaine 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Lidocaine HCl……..…...40 mg (USP Specification)
	Pharmaceutical form of applied drug	Anesthetic (Local), Antiarrhythmic (Class IB)
	Pharmacotherapeutic Group of (API)	Clear, colourless transparent solution filled in 2ml Clear glass ampoule USP type 1
	Reference to Finished product specifications	USP
	Proposed Pack size	2mlx5's, 2mlx10's, 2mlx25's, 2mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lidocaine 2% w/v solution for injection by Hameln pharma ltd, of MHRA approved
	For generic drugs (me-too status)	Xylex 2% Injection of M/s Venus pharma, (Reg. No. 012958)
	Name and address of API manufacturer.	M/s Gufic Biosciences Limited. N,H. No. 8 Near Grid, At & PO kabilpore-396 424 Navsari India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Surgicain injection manufactured by Harmann Pharmaceutical Laboratories Pvt. Ltd by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Gufic Biosciences Limited. N,H. No. 8 Near Grid, At &PO kabilpore-396 424 Navsari India		
API Lot No.	API/LIH/202161		
Description of Pack (Container closure system)	2ml x 100's Ampoules		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LT-001	LT-002	LT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	21-03-2023	21-03-2023	21-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.20081523) dated 07-08-2020 issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 06-08-2023

3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between M/s DS pharma and M/s NS pharma submitted. Firm has submitted copy of form 5 and Commercial Invoice #NBEXBD2021000224, dated; 10-12-2020 cleared by DRAP (Lahore) dated: 19-01-2021 specifying. Lidocaine HCL Batch # API/LIH/202161 (M/s NS pharma)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted the audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of GMP Certificate (No.22093515) dated 05-09-2022 issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 04-09-2025
2.	2.3.R.1.1	• Overage is used in stability batches. Reference product specify Each 1 ml contains 20.0 mg of lidocaine hydrochloride, corresponding to 16.2 mg lidocaine while your product contains Each ml contains 21.28mg. Clarify. • How pH is adjusted without Hydrochloric Acid & Sodium Hydroxide.	• As our label claim is Lidocain as HCl and the factor of lidocaine hydrochloride is 1.064. So by applying factor (20 × 1.064 = 21.28 mg) . here potency of HCl salt is adjusted. ***(As per reference product 20mg lidocaine Hydrochloride* corresponding to 16.2 mg lidocaine. Lidocaine as HCl is not available in RRA.)** • The pH of the injection is adjusted with 1M HCl or 1M NaOH when necessary. Revised formulation mentioning this is attached.
3.	3.2.S.4.3	• In analytical Method Verification studies in accuracy and precision what concentrations is used. • In analytical Method Verification studies specificity of drug substance which Placebo is used.	• Revised method verification is attached. • Placebo term here represent diluent/medium in specificity of drug substance method verification.
4.	3.2.S.4.4	Drug substance manufacturer applied on BP monograph while you have mentioned on USP monograph.	We have applied USP method for drug substance and also verified it and submitted its record.
5.	3.2.P.1	In reference product Hydrochloric Acid & Sodium Hydroxide are used for pH adjustment while in your product these are not added than how pH adjustment is done.	The pH of the injection is adjusted with 1M HCl or 1M NaOH when necessary. Revised formulation mentioning this is attached.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	No preservative is used in the formulation so preservative effectiveness studies is not applicable. effectiveness study

7.	3.2.P.5.1	Bacterial Endotoxin test and particulate matters are not part of specification as specified in USP monograph. Clarify.	We have performed Bacterial endotoxin and particulate matter test. Revised specifications is attached.
8.	3.2.P.5.3	Analytical Method Verification studies Concentrations are not as per USP monograph concentrations.	Revised method Verification documents are attached.
9.	3.2.P.7	Submit details of primary Container Closure System.	Filled in 2cc amber colored Type-1 glass.
10.	3.2.P.8	• Sterility test and Bacterial Endotoxin test are not part of stability studies. • Submit complete Raw data for stability studies . • Submit 6th month stability studies data.	• We have performed sterility test and bacterial endotoxin test during stability studies. • Raw data for stability studies is not submitted**.** • 6th month stability studies data submitted

Previous Decision (M-333): Registration Board deferred the case for following:

- Revision of label claim as per reference product along with submission of fee of Rs:30000/- for preregistration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
- Submission of complete Raw data for stability studies of 03 batches.

S.No	Reason of deferment	Reply
1.	Revision of label claim as per reference product along with submission of fee of Rs:30000/- for pre registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	We are going to change our salt from Lidocain as HCl to Lidocain HCl Label claim is changed as per reference product without submission of fee that is**:** Each 2ml Ampoule Contains: Lidocaine HCl……..…...40 mg
2.	Submission of complete Raw data for stability studies of 03 batches.	Complete Raw data for stability studies of 03 batches submitted.

Decision: Approved. Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of Label claim), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

721.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 16135 dated 26-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 3711866112
	The proposed proprietary name / brand name	**Ds-B12 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Cyanocobalamin……..…….1000 mcg (USP Specification)
	Pharmaceutical form of applied drug	Corrinoids (Vitamin b12)
	Pharmacotherapeutic Group of (API)	Clear, red colour solution filled in amber coloured glass ampoule
	Reference to Finished product specifications	USP
	Proposed Pack size	2mlx5's, 2mlx25's, 2mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	B12 Steigerwald solution for injection by Bayer Vital GmbH (**Germany** Approved)
	For generic drugs (me-too status)	Vitamin B-12 1000mcg/2ml Injection of M/s Avensis Pharmaceuticals(Reg. No. 012091)
	Name and address of API manufacturer.	Hebei Yuxing Bio-Engineering Co. Ltd Address: Xicheng District, Ningjin country, Xing Tai city, Hebei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product B12 injection manufactured by Venus pharma.by performing quality tests Identification, , pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Hebei Yuxing Bio-Engineering Co. Ltd Address: Xicheng District, Ningjin country, Xing Tai city, Hebei Province, China		
API Lot No.	C200504F		
Description of Pack (Container closure system)	2ml x 25's Ampoules		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BT-001	BT-002	BT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HE20190142) dated 30-11-2019 issued by China Food and Drug Administration. The certificate is valid till 29-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Testing is done by UV method
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.5.5	Submit Correct pharmacological group with submission of requisite fee.	Correction of pharmacological group without submission of fee as follows: Supplement for Vitamin B12 Deficiency

2.	1.5.6	No specification are claimed in this section.	Our product specifications are USP. Revised document is attached.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted in accordance to USP monograph.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) submitted as per USP monograph.
4.	3.2.S.P.1	• Benzyl Alcohol and Sodium dihydrogen phosphate are not used by reference product while used in your formulation. Clarify or submit compatibility studies. • Hydrochloric acid 8.5% is used by reference product while it is not in you product. Clarify.	• Our product is stable in this formulation and also performed compatibility studies and report is attached. • We adjusted pH with HCl 8.5% when necessary.
5.	3.2.P.5.1	Bacterial Endotoxin test is not part of specification as specified in USP monograph. Clarify.	Revised specifications with Bacterial Endotoxin submitted.
6.	3.2.P.5.3	Analytical Method Verification studies Concentrations are not as per USP monograph concentrations. Clarify.	Revised analytical method Verification studies as per USP monograph submitted.
7.	3.2.P.7	Submit details of primary Container Closure System.	Filled in 2cc amber coloured Type-1 glass.
8.	3.2.P.8	• Submit Import documents in clear form.. • Submit complete Raw data for stability studies . • Submit 6th month stability studies data.	• An agreement of API's Loan between M/s DS pharma and M/s NS pharma submitted. Firm has submitted copy of Commercial Invoice #20KLM-0727A, dated; 27-07-2020 cleared by DRAP (Lahore) dated: 29-10-2020 specifying. Cyanocobalamin Batch # C200504F (M/s NS pharma). • Raw data for stability studies submitted. • 6th month stability studies data submitted.

Previous Decision (M-333): Registration Board Deferred the case for submission of complete Raw data for stability studies of 03 batches.

S.No	Reason of deferment	Reply
1.	Registration Board Deferred the case for submission of complete Raw data for stability studies of 03 batches.	Complete Raw data for stability studies of 03 batches submitted.

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

722.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate in dated 17-12-2020 specifying Injection (General) section.
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 10057 dated 20-04-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 8289699040
	The proposed proprietary name / brand name	Amicable Injection 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Amikacin as sulfate……250mg
	Pharmacotherapeutic Group of (API)	Injection
	Pharmaceutical form of applied drug	Antibacterial Aminoglycosides
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	2ml x1's, 2ml x 2's, 2ml x 5's, 2ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Amikacin solution for Injection Manufacturer Hospira UK Limited
	For generic drugs (me-too status)	Grasil Injection 500mg Manufactured by Sami Pharm (Pvt) Ltd Reg# 014251
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China (Peviously Qilu Tianhe Pharmaceuticals co.,Ltd)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months

		Batches: 120835205A, 120835505A, 120835805A
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is Grasil Injection by Sami Pharm (Pvt) Ltd performing quality tests (Identification, Physical appearance, Clarity, Endotoxin test, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** Shandong Anxin Pharmaceutical Co., Ltd **Address:** No. 10678 Wenliang Road, Dongjia Town, Licheng District, Jinan, China		
API Lot No.	RA0273A		
Description of Pack (Container closure system)	Schott Glass USP type-1 amber glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	11-07-2021	11-07-2021	11-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product Dascot 30mg & 60mg Tablet which was conducted on 26-01-2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 specifying Amikacin sulphate 3Kg, Dated: 13-10-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming
1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same fill volume i.e 1ml in one of the reference regulatory authority specified by Registration Board

Previous Decision (M-331): Deferred for evidence of approval of applied formulation in the same fill volume i.e 1ml in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

S.No	Reason of deferment	Reply
1.	Deferred for evidence of approval of applied formulation in the same fill volume i.e 1ml in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	With reference to the subject cited above, our product Amicable Injection 500mg (Each ml contains: Amikacin as sulfate 250mg) was evaluated and required justification of filled volume 1 ml We conducted a stability study with a 1 ml filled volume, whereas the innovator product has a filled volume of 2 ml. However, the concentration of amikacin sulfate of innovator product is 250mg per 1 ml. The label claim for the mentioned product aligns with that of the Innovator's products Therefore, we request you to kindly grant us approval of the aforementioned product in the upcoming meeting of the Drug Registration Board (DRB) at your earliest convenience as the filled volume does not affect the quality of the product.

Remarks of Evaluator:

S.No	Section	Shortcoming
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	2.3.R.1.1	In batch manufacturing record of 3 batches dispensing sheets are not submitted.
4.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
5.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient Drug Product manufacturer is required
6.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.

	7.	3.2.S.4.4	• Certificate of Analysis (CoA) of the same batch of drug substance from Drug Substance / /Active Pharmaceutical Ingredient manufacture which are used during product development and stability studies by drug product manufacturer. • As per BP monograph sulfate content deducted which is not done by you. Justification is required.
	8.	3.2.S.4.5	Justification of specification are as per USP monograph while BP monograph is used by drug product manufacturer for drug substance., Clarify
	9.	3.2.P.2.2.1	Provide details of product against which Pharmaceutical Equivalence conducted.
	10.	3.2.P.5.2	BP monograph specify detection wavelength 340nm while your analytical method specify detection wavelength 200nm. Clarify how on 200nm detection done.
	11.	3.2.P.8	Documents for the procurement of API with approval from DRAP

Proceedings of 336th meeting; In 331st meeting, the produt was deferred for one point i.e, availability of 2 ml volume in RRA and it was afound that the said volume is approved by MHRA/EMA and available in EMC.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

723.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: 42M-8WQ-4XDN Application No. 1463 dated 11-03-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # 857795793779
	The proposed proprietary name / brand name	Surgisys Eye Drop (0.4 % Polyethylene Glycol 400 and 0.3% Propylene Glycol Ophthalmic Solution)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Polyethylene Glycol 400 …. 4 mg Propylene Glycol ……3 mg
	Pharmacotherapeutic Group of (API)	Lubricant Eye Drops
	Reference to Finished product specifications	Innovator's specs

EVALUATION OF DATA

GMP status of the firm	New DML issued dated: 08-11-2022
Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
Proposed Pack size	15ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	SYSTANE LUBRICANT by Alcon Laboratories, Inc of (OTC product in USFDA)
For generic drugs (me-too status)	Systane by M/s Alcon Laboratories, Inc.Reg # 044834

Name and address of API manufacturer.	PROPYLENE GLYCOL: Shandong Shida Shenghua Chemical 198, Tongxing Road, Kenli District, Dongying City, Shandong-China Polyethylene glycol: Anhui Eapearl Chemical Co.Ltd. Economic Development Zone TOngling City, Anhui Province CHINA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Propylene Glycol: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. Polyethylene Glycol 400 : Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Systane ophthalmic Solution Manufactured by Alcon Laboratories.
Analytical method validation/verification of product	

STABILITY STUDY DATA

API Lot No.	Propylene Glycol:IP03-202212107 Polyethylene Glycol 400 : EP20230414H		
Description of Pack (Container closure system)	HDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SYS-TRIAL001	SYS-TRIAL002	SYS-TRIAL003
Batch Size	15 L (1000 Packs)	15 L (1000 Packs)	15 L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	11-2022	11-2022	11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
Documents for the procurement of API with approval from DRAP (in case of import).	
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (No.IV):

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol
4.	3.2.S.4.4	Submit COA of both drug substances by drug substance manufacturer and drug product manufacturer with batch No used during product development and stability studies
5.	3.2.P.1	Reference product add hydrochloric acid and/or sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
6.	3.2.P.5.1	Submit specification of applied product.
7.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided for both Propylene Glycol and Polyethylene Glycol.
8.	3.2.P.8	Documents for the procurement of API with approval from DRAP

Previous Decision (335): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol	Copies of the Drug substance specifications by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol are submitted.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol are submitted.
4.	3.2.S.4.4	Submit COA of both drug substances by drug substance manufacturer and drug product manufacturer with batch No used during product development and stability studies	COA of both drug substances by drug substance manufacturer and drug product manufacturer submitted.

5.	3.2.P.1	Reference product add hydrochloric acid and/or sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.	HCl solution is used to adjust the pH and evident from batch manufacturing record.
6.	3.2.P.5.1	Submit specification of applied product.	Specifications of applied product submitted.
7.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided for both Propylene Glycol and Polyethylene Glycol.	COA of primary / secondary reference standard including source and lot number shall be provided for both Propylene Glycol and Polyethylene Glycol submitted.
8.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API with approval from DRAP submitted.

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

724.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited 7, Jail Road Quetta, Pakistan
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited 7, Jail Road Quetta, Pakistan **BULK API MANUFACTURER:** Fresenius Kabi Austria GmbH Estermannstraße 17 4020 Linz Austria, Europe
	Status of the applicant	☒ Manufacturer (Bulk import local repack) ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6613: 01-03-2021
	Details of fee submitted	PKR 100,000/-: 11-02-2021
	The proposed proprietary name / brand name	**Laxocare Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Lactulose Solution USP …. 3.35g
	Pharmaceutical form of applied drug	**Syrup**
	Pharmacotherapeutic Group of (API)	LAXATIVE
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	120ml & 240ml
	Proposed unit price	AS PER DPC
	The status in reference regulatory authorities	DUPHALAC of Mylan MHRA Approved

	For generic drugs (me-too status)	DUPHALAC of M/s Abbott Laboratories (Reg. No.: 06655)
	GMP status of the Finished product manufacturer	Certificate of cGMP on the basis of inspection conducted on 15 & 16, August 2018
	Name and address of API manufacturer.	Fresenius Kabi Austria GmbH Estermannstraße 17 4020 Linz Austria, Europe
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Remarks: Firm has performed Pharmaceutical equivalence against the product i.e DUPHALAC of M/s Abbott Laboratories and the results are within acceptable limit.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed Pharmaceutical equivalence against the product i.e DUPHALAC of M/s Abbott Laboratories , and the results are within acceptable limit	

STABILITY STUDY DATA			
Manufacturer of API	Fresenius Kabi Austria GmbH Estermannstraße 17 4020 Linz Austria, Europe		
API Lot No.	17190532		
Description of Pack (Container closure system)	Amber glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	5 Liter	5 Liter	5 Liter
Manufacturing Date	02.2020	02.2020	02.2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (Certificate No.INS-480019-0063-011) for M/s Fresenius Kabi Austria GmbH Estermannstraße 17 4020 Linz issued by Austria on the basis of Inspection conducted on 24-09-2018 and, valid for three Year.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Evaluation:

S.No	Section	Shortcomings Communicated
1.	1.1	In covering letter label claim is 33.5 gm. Clarification is required in this regard.
2.	1.5.2.	Strength of API is 3.35mg. Clarification is required in this regard.
3.	3.2.S.4	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance before initiation of stability studies and manufacturing however you are performing after completion of 6 month of stability studies. Clarification is required.
4.	3.2.P.3	A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified shall be submitted by Drug product manufacturer.
5.	3.2.P.3.3	Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled , shall be submitted by Drug product manufacturer.
6.	3.2.P.5	Provide Evidence of RI detector
7.	3.2.P.5	As per relevant guidelines & structure of Form 5F Analytical test method validation has to be performed at the time of formulation development, while according to your submitted data, Analytical test method validation protocols has been approved after commencement of stability studies as well as Analytical test method validation have been performed on 29-10-2020 while stability studies started on 02-2020. Justification shall be submitted in this regard.
8.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Stability initiation date mentioned is 02-2020 while initial testing conducted in march

Previous Decision (M-324): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months**.**

Evaluation:

S.No	Section	Shortcomings Communicated	Reply
1.	1.1	In covering letter label claim is 33.5 gm. Clarification is required in this regard.	In covering letter, it was typographic error, correct strength is 3.35gm

2.	1.5.2.	Strength of API is 3.35mg. Clarification is required in this regard.	Strength of API is 3.35g, same is mentioned in Application form (Copy of form is enclosed), However 1.5.2 referred section mentioned strength is due to typographical error
3.	3.2.S.4	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance before initiation of stability studies and manufacturing however you are performing after completion of 6 month of stability studies. Clarification is required.	• Validation of analytical procedure for detection of Lactulose as per USP was already performed by Drug Substance manufacturer (DMF attached) and this product is ready to fill product and we have only filled the product in bottles and there was no formulation and mixing. • As this product is only ready to fill and no additional excipients which could interfere with detection of API, therefore. Analytical method validation done by drug substance manufacturer is deemed valid. • As this is a United States Pharmacopeia method which is not required method validation hence only verification is done. Furthermore, this is only ready to fill product and validation of testing method is also done by drug product manufacturer which has been provided with dossier
4.	3.2.P.3	A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified shall be submitted by Drug product manufacturer.	Submitted
5.	3.2.P.3.3	Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled , shall be submitted by Drug product manufacturer.	Submitted.
6.	3.2.P.5	Provide Evidence of RI detector	Calibration certificate of RI detector along with pictures of RI detector showing serial no. is attached
7.	3.2.P.5	As per relevant guidelines & structure of Form 5F Analytical test method validation has to be performed at the time of formulation development, while according to your submitted data, Analytical test method validation protocols has been approved	We have performed some pre-validation studies which includes limited parameters (Linearity, accuracy and specificity) at the time of method development activity to assure that the method is capable of its intended purpose, however the complete validation will be conducted later on, In case of Laxocare syrup 3.35g/5ml, pre-validation activity found satisfactory results.

		after commencement of stability studies as well as Analytical test method validation have been performed on 29-10-2020 while stability studies started on 02-2020. Justification shall be submitted in this regard.	
8.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Stability initiation date mentioned is 02-2020 while initial testing conducted in march	• Firm submitted Loan agreement from Rasco Pharma. • Firm has submitted copy Commercial Invoice # 1370054582, dated; 03-12-2019 cleared by DRAP (Lahore) dated: 24-12-2019 specifying Cholecalciferol batch # 17190532. • This Product is ready to fill product which does not involve any additional excipient and mixing, and drug product was tested before filling operation. Hence quality of drug product was already confirmed, therefore stability studies initiated just after filling operation in February 2020 and just confirmation testing of filled samples was done in March 2020 which is considered as Initial testing.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Qadir Pharmaceuticals**. (New DML)**

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following seven (07) sections to M/s Qadir Pharmaceuticals

1. Tablet (General)
2. Capsule (General)
3. Oral Liquid (General)
4. Liquid Injectable – Vial & Ampoule (General)
5. Capsule (Cephalosporin)
6. Dry Powder Injectable (Cephalosporin)
7. Oral Dry Powder Suspension (Cephalosporin)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

Tablet Section (General)		
725.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Cream Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: M1Y-QNY-T2R6 Application No. 1498 dated 16-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 3150282053
	The proposed proprietary name / brand name	Epilept 100mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….…….100mg
	Pharmaceutical form of applied drug	Antiepileptic agent
	Pharmacotherapeutic Group of (API)	white color round shape film coated tablet, plain on both sides.
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 100mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073858)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility’s, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 100mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 100mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	LE2210006		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR046	TTR047	TTR048
Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	15-02-2023	15-02-2023	15-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-K-1458307553412 issued on 12/01/2023 by Drug Regulatory Authority of Pakistan, Karachi valid till 11/01/2025 specifying LACOSAMIDE was provided. Firm has submitted copy of form 3, form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-

		2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The copy of batch manufacturing record (BMR) for all the batches of drug products for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. ***Firm claimed Ph. Eur while submitted method is as per USP monograph of drug product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.***
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer. ***Verification studies of previously submitted for drug product is submitted for drug substance***.
5.	3.2.S.4.4	Certificate of Analysis (CoA) of the same batch of Drug Substance by both Drug substance manufacturer and Drug Product manufacturer used during product development and stability studies.	Certificate of analysis (COA) of the same batch of drug substance by both drug substance manufacturer and drug product manufacturer used during product development and stability studies are attached.

6.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
7.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
8.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached
9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end. ***Method in verification studies submitted as per USP monograph . Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.***
10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Previous Decision(M-335): Deferred for submission of following:

- Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
- Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method**.**

Evaluation:

S.No	Reason of deferment	Reply
1.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.	Revised analytical method as per USP monograph submitted.
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance submitted.

3.	Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.	Revised analytical method verification submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

726.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Tablet Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: X15-U94-5UBG Application No. 1493 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 40000970065
	The proposed proprietary name / brand name	Epilept 50mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….50mg
	Pharmaceutical form of applied drug	white color round shape film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Antiepileptic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 50mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073857)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 50mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 50mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	LE2210006		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR043	TTR044	TTR045

Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	14-02-2023	14-02-2023	14-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The copy of batch manufacturing record (BMR) for all the batches of drug products for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. ***Firm claimed Ph. Eur while submitted method is as per USP monograph of drug product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.***
4.	3.2.S.4.3	Analytical Method Verification studies including specificity,	Analytical method verification studies including specificity, accuracy and

		accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	repeatability (method precision) of drug substance performed by the drug product manufacturer. ***Verification studies of previously submitted for drug product is submitted for drug substance***.
5.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
6.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
7.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached
8.	3.2.P.2.2.1	2 different buffers and pH i.e Citrate buffer with pH 6.6 & Phosphate buffer with pH 6.8 are mentioned in Comparative dissolution profile . Clarify which buffer is used in Comparative dissolution profile. Clarification is required.	Phosphate buffer with pH 6.8 is used in comparative dissolution profile. May be there is some mistake in writing the correct CDP is attached.
9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end. ***Method in verification studies submitted as per USP monograph . Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.***
10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Previous Decision(M-335): Deferred for submission of following:

- Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
- Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method**.**

Evaluation:

S.No	Reason of deferment	Reply
4.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.	Revised analytical method as per USP monograph submitted.
5.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance submitted.
6.	Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.	Revised analytical method verification submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

727.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Tablet Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: X7G-YX1-D7VW Application No. 1520 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 034819025601
	The proposed proprietary name / brand name	Epilept 150mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….…….150mg
	Pharmaceutical form of applied drug	white color round shape film coated tablet, plain on both sides.

	Pharmacotherapeutic Group of (API)	Antiepileptic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 150mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073859)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 150mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 150mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	LE2210006		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR049	TTR050	TTR051
Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	15-02-2023	14-02-2023	14-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The copy of batch manufacturing record (BMR) for all the batches of drug products for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.

		Drug Product manufacturer is required.	
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. ***Firm claimed Ph. Eur while submitted method is as per USP monograph of drug product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.***
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer. ***Verification studies of previously submitted for drug product is submitted for drug substance***.
5.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
6.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
7.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached
8.	3.2.P.2.2.1	2 different buffers and pH i.e Citrate buffer with pH 6.6 & Phosphate buffer with pH 6.8 are mentioned in Comparative dissolution profile . Clarify which buffer is used in Comparative dissolution profile. Clarification is required.	Phosphate buffer with pH 6.8 is used in comparative dissolution profile. May be there is some mistake in writing the correct CDP is attached
9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end.

			Method in verification studies submitted as per USP monograph . Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.
10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Previous Decision(M-335): Deferred for submission of following:

- Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
- Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method**.**

Evaluation:

S.No	Reason of deferment	Reply
7.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.	Revised analytical method as per USP monograph submitted.
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance submitted.
9.	Justify for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.	Revised analytical method verification submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

728.	**Name and address of manufacturer / Applicant**	**M/s Rogen Pharmaceuticals (Pvt.) Ltd. Plot #: 30, Street No. S-4, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Omegen Sachet 20mg
	Composition	Each Sachet contains: Omeprazole……20mg
	Diary No. Date of R& I & fee	DyNo.19812; 30-05-2018; Rs. 20,000/-
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	New Section (Issuance Date: 19th December 2017)
	Remarks of the Evaluator	
	Previous Decision	Registration Board in its 283rd meaning deferred the case for following reasons: For Submission Of Fee For Revision Of Formulation From Omeprazole 20mg To Omeprazole 20mg & Sodium Bicarbonate 1100mg Sachet
	Evaluation by PEC (AD PEC-VIII)	Applicant has submitted required fee of Rupee Rs 20,000 dated 04-09-18 for the change in formulation which is in line with reference Now. New composition is as follow: Each Sachet contains: Omeprazole……20mg Sodium bicarbonate……1680mg RRA Reference: Approved in USFDA (ZEGERID (omeprazole and sodium bicarbonate) for oral suspension) Me Too: Risek Insta Sachet 20mg + 1680mg of Getz Pharma
	Previous Decision (287-DRB)	Deferred for further deliberation upon consideration of revision of formulation with addition of API, against the queue of previously submitted application
	Evaluation by PEC	
	Previous Decision (M-307): Deferred for updated status of GMP of the firm from QA & LT division	
	Firm submitted last Inspection report of dated: 28 & 30/05/2022 for renewal of DML and report concludes that based on areas inspected and considering the findings of inspection, it is concludes that firm may be considered to be operating at an acceptable.	
	Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Case no. 03 Registration applications of categories to be considered on priority

a. Export facilitation

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-I(EFD). dated 28-02-2023 has informed that The M/s Nabiqasim Industries has achieved benchmark of USD 1433148.8 during fiscal year 2020-2021 and requested for priority consideration of following molecule the (1 molecule) 03 products:.		
729.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32615 dated 14-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 0320515010
	The proposed proprietary name / brand name	Preneu CR 82.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Pregabalin…….82.5mg
	Pharmacotherapeutic Group of (API)	Extended Release film coated tablets
	Pharmaceutical form of applied drug	Antiepileptic
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	14's, 20's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5% for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the LYRICA CR Tablet by Pfizer pharma singapore by performing quality tests (Identification, Assay, Disintegration, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LYRICA CR Tablet by Pfizer pharma Singapore . in Acid media (pH 1.0-1.2) 0.06N HCl & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA		
Manufacturer of API	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India	
API Lot No.	PG-1021119	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	572DS01	572DS02
Batch Size	5000 Tablets	5000 Tablets
Manufacturing Date	12-2021	12-2021
Date of Initiation	31-12-2021	31-12-2021
No. of Batches	03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on 26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. S-GMP & GLP/24044908) issued by Food & Drug Control Administration Gujrat state India. issued dated:03-04-2024 and valid till 02-04-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 7, and Commercial Invoice # 044 dated: 23-11-2019 cleared by DRAP (Karachi) on 18-12-2019 specifying 150Kg of Pregabalin batch # PG-1021119.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	submitted.
2.	3.2.S.4.2 & 3.2.S.4.3	In analytical testing method of assay for drug substance wavelength is not mentioned.	In analytical testing method of assay for drug substance the wavelength is mentioned under heading Parameters, mention on page no. 10 of monograph is enclosed.
3.	3.2.S.5	Submit COA of Pregabalin Related compound A used in enantiomeric purity	Submitted.
4.	3.2.P.2.2.1	Submitted CDP data is in 0.06N HCl instead of 0.1 N HCl. Justification is required.	Reference to WHO Technical Report Series No. 1003,2017 studies should be performed in at least three media covering the physiological range including pH 1.2 HCl, pH 4.5 buffer and pH 6.8 buffers. We have selected QC release media 0.06N HCl whose pH is also equivalent to pH 1.2 fulfilling the pH range of physiological buffers to conduct CDP studies.
5.	3.2.P.5.2	In analytical testing method of assay for drug product wavelength is not mentioned.	In drug product testing method, for assay test the wavelength is mentioned under heading Chromatographic condition mention on page no. 4 of monograph is enclosed .
6.	3.2.P.5.3	Submit complete report of Accuracy parameter in analytical method validation.	Submitted.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

730.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31581 dated 03-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 2245763220
	The proposed proprietary name / brand name	Preneu CR 165mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Pregabalin…….165mg
	Pharmacotherapeutic Group of (API)	Extended Release film coated tablets
	Pharmaceutical form of applied drug	Antiepileptic
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	14's, 20's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5% for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process

		control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the LYRICA CR Tablet by Pfizer pharma singapore by performing quality tests (Identification, Assay, Disintegration, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LYRICA CR Tablet by Pfizer pharma Singapore . in Acid media (pH 1.0-1.2) 0.06N HCl & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA		
Manufacturer of API	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India	
API Lot No.	PG-1021119	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	573DS01	573DS02
Batch Size	5000 Tablets	5000 Tablets
Manufacturing Date	12-2021	12-2021
Date of Initiation	03-01-2021	03-01-2021
No. of Batches	03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on 26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. S-GMP & GLP/24044908) issued by Food & Drug Control Administration Gujrat state India. issued dated:03-04-2024 and valid till 02-04-2026.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 7, and Commercial Invoice # 044 dated: 23-11-2019 cleared by DRAP (Karachi) on 18-12-2019 specifying 150Kg of Pregabalin batch # PG-1021119.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Submitted.
2.	3.2.S.4.2 & 3.2.S.4.3	In analytical testing method of assay for drug substance wavelength is not mentioned.	In analytical testing method of assay for drug substance the wavelength is mentioned under heading Parameters, mention on page no. 10 of monograph is enclosed
3.	3.2.S.5	Submit COA of Pregabalin Related compound A used in enantiomeric purity	Submitted
4.	3.2.P.2.2.1	Submitted CDP data is in 0.06N HCl instead of 0.1 N HCl. Justification is required.	Reference to WHO Technical Report Series No. 1003,2017 studies should be performed in at least three media covering the physiological range including pH 1.2 HCl, pH 4.5 buffer and pH 6.8 buffers. We have selected QC release media 0.06N HCl whose pH is also equivalent to pH 1.2 fulfilling the pH range of physiological buffers to conduct CDP studies.
5.	3.2.P.5.2	In analytical testing method of assay for drug product wavelength is not mentioned.	In drug product testing method, for assay test the wavelength is mentioned under heading Chromatographic condition mention on page no. 4 of monograph.
6.	3.2.P.5.3	• In analytical method validation protocol test solution preparation how 1 tablet weight is equivalent to 82.5mg while applied strength is 165mg. • Submit complete report of Accuracy parameter in analytical method validation.	• We have incorporated sample preparation method for 165mg tablet strength in analytical method validation protocol. • Submitted**.**

Decision: Approved with innovator's specification.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
731.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31580 dated 03-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 4452187896
	The proposed proprietary name / brand name	Preneu CR 330mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Pregabalin…….330mg
	Pharmacotherapeutic Group of (API)	Extended Release film coated tablets
	Pharmaceutical form of applied drug	Antiepileptic
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	14’s, 20’s, 28’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility’s, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the LYRICA CR Tablet by Pfizer pharma singapore by performing quality tests (Identification, Assay, Disintegration, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LYRICA CR Tablet by Pfizer pharma Singapore . in Acid media (pH 1.0-1.2) 0.06N HCl & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA		
Manufacturer of API	Atlas Life Sciences Private limited C-1/360-361, G.I.D.C. Estate, Ahmedabad- Gujrat, India	
API Lot No.	PG-1021119	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	574DS01	574DS02
Batch Size	5000 Tablets	5000 Tablets
Manufacturing Date	12-2021	12-2021
Date of Initiation	03-01-2021	03-01-2021
No. of Batches	03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on

		26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. S-GMP & GLP/24044908) issued by Food & Drug Control Administration Gujrat state India. issued dated:03-04-2024 and valid till 02-04-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 7, and Commercial Invoice # 044 dated: 23-11-2019 cleared by DRAP (Karachi) on 18-12-2019 specifying 150Kg of Pregabalin batch # PG-1021119.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Submitted.
2.	3.2.S.4.2 & 3.2.S.4.3	In analytical testing method of assay for drug substance wavelength is not mentioned.	In analytical testing method of assay for drug substance the wavelength is mentioned under heading Parameters, mention on page no. 10 of monograph is enclosed
3.	3.2.S.5	Submit COA of Pregabalin Related compound A used in enantiomeric purity	Submitted
4.	3.2.P.2.2.1	Submitted CDP data is in 0.06N HCl instead of 0.1 N HCl. Justification is required.	Reference to WHO Technical Report Series No. 1003,2017 studies should be performed in at least three media covering the physiological range including pH 1.2 HCl, pH 4.5 buffer and pH 6.8 buffers. We have selected QC release media 0.06N HCl whose pH is also equivalent to pH 1.2 fulfilling the pH range of physiological buffers to conduct CDP studies.
5.	3.2.P.5.2	In analytical testing method of assay for drug product wavelength is not mentioned.	In drug product testing method, for assay test the wavelength is mentioned under heading Chromatographic condition mention on page no. 4 of monograph.

6.	3.2.P.5.3	• In analytical method validation protocol test solution preparation how 1 tablet weight is equivalent to 82.5mg while applied strength is 330mg. • Submit complete report of Accuracy parameter in analytical method validation.	• We have incorporated sample preparation method for 330mg tablet strength in analytical method validation protocol. • Submitted.

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-II(EFD). dated 24-03-2024 has informed that The M/s Werrick Pharmaceuticals has achieved benchmark of USD 10030 during fiscal year 2017-2018 and requested for priority consideration of following molecule the (1 molecule) 02 products:.

732.	Name, address of Applicant / Marketing Authorization Holder	M/S Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/S Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 22-08-2022 on the basis of evaluation conducted on 18-08-2021 and valid for 2 years till 11-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 29-11-2022 specifying Tablet General.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24775dated 11-10-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip# 7405733733
	The proposed proprietary name / brand name	**Vono-Tab 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……... 10mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blocker (P-CAB). WHO ATC CODE**:** A02BC08
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	Innovator's product.
	Proposed Pack size	7 's, 10 's, 14 's, 20 's, 28 's, 30 's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg Tablets (PMDA Japan Approved)
	For generic drugs (me-too status)	Vonozan 10mg Tablets of M/s Getz Pharma Reg# 108570
	Name and address of API manufacturer.	Ami Lifesciences Pvt.Ltd. **Address:** Block No. 82/B, Ecp Road, At & Post. Karakhadi, Taluka-Padra, District Vadodara Gujarta, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5%RH for 24months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Vonozan 10mg Tablet manufactured by Getz pharma performing quality tests (Identification, Hardness, Disintegration, Assay, Dissolution test). CDP has been performed against the Vonozan 10mg Tablet manufactured by Getz pharma in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	Ami Lifesciences Pvt.Ltd. **Address:** Block No. 82/B, Ecp Road, At & Post. Karakhadi, Taluka-Padra, District Vadodara Gujarta, India
API Lot No.	VPF30040821

Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-01
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	18-01-2023	24-01-2023	25-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	•
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . 22043267 issued by food and Drug Control administration Gandhinagar Gujarat State India valid until 17.04.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3 and form 7, commercial invoice # EXP/I/21-22/0515 dated: 30-11-2021 cleared by DRAP (Islamabad) dated:03-01-2022 specifying 0.325Kg of Vonoprazan Fumarate batch # VPF30040821
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Potency of Vonoprazan Fumarate mentioned in BMR is 74.85%. while potency in COA is 99.01%.	In BMR 74.85% is not the potency of Vonoprazan fumarate. It is the base activity of Vonoprazan in Vonoprazan Fumarate which is adjusted in formulation as per label claim while 99.01% is the assay of drug substance Vonprazan Fumarate.
2.	3.2.S.7	Submit drug substance stability studies till claimed shelf life.	Submitted
3.	3.2.P.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted in this regard.	Submitted

Decision: Approved with innovator's specification.. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
733.	Name, address of Applicant / Marketing Authorization Holder	M/S Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/S Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 22-08-2022 on the basis of evaluation conducted on 18-08-2021 and valid for 2 years till 11-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 29-11-2022 specifying Tablet General.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26295 dated 31-10-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip# 9272358160
	The proposed proprietary name / brand name	**Vono-Tab 20mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……... 20mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blocker (P-CAB). WHO ATC CODE**:** A02BC08
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	Innovator's product.
	Proposed Pack size	7 's, 10 's, 14 's, 20 's, 28 's, 30 's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg Tablets (PMDA Japan Approved)
	For generic drugs (me-too status)	Vonozan 20mg Tablets of M/s Getz Pharma Reg# 108571
	Name and address of API manufacturer.	Ami Lifesciences Pvt.Ltd. **Address:** Block No. 82/B, Ecp Road, At & Post. Karakhadi, Taluka-Padra, District Vadodara Gujarta, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 24months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Vonozan 20mg Tablet manufactured by Getz pharma performing quality tests (Identification, Hardness, Disintegration, Assay, Dissolution test). CDP has been performed against the Vonozan 20mg Tablet manufactured by Getz pharma in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Ami Lifesciences Pvt.Ltd. **Address:** Block No. 82/B, Ecp Road, At & Post. Karakhadi, Taluka-Padra, District Vadodara Gujarta, India		
API Lot No.	VPF30040821		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-01
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	20-02-2023	27-02-2023	28-02-2023

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	•
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . 22043267 issued by food and Drug Control administration Gandhinagar Gujarat State India valid until 17.04.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3 and form 7, commercial invoice # EXP/I/21-22/0515 dated: 30-11-2021 cleared by DRAP (Islamabad) dated:03-01-2022 specifying 0.325Kg of Vonoprazan Fumarate batch # VPF30040821
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Potency of Vonoprazan Fumarate mentioned in BMR is 74.85%. while potency in COA is 99.01%.	In BMR 74.85% is not the potency of Vonoprazan fumarate. It is the base activity of Vonoprazan in Vonoprazan Fumarate which is adjusted in formulation as per label claim while 99.01% is the assay of drug substance Vonprazan Fumarate.
2.	3.2.S.7	Submit drug substance stability studies till claimed shelf life.	Submitted
3.	3.2.P.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted in this regard.	Submitted

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 04 Registration applications of import cases

c. Deferred cases

i. Human

734.	Name, address of Applicant / Importer	M/s. Al Habib Pharmaceuticals, **Address:** Plot # 81, Block B, SMCHS, Karachi – Pakistan
	Details of Drug Sale License of importer	**License No:** 0230 **Address:** Plot # 81, Block B, SMCHS, Karachi – Pakistan

		Address of Godown: NA **Validity:** 18-05-2024 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name, address of manufacturer(s)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# COPP/CERT/KD/100457/2021/11/34994/172799) Valid up to 03-04-2022 by , Food and Drug control administration Gujrat state india **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Yearly. (Section of Tablet cytotoxic mentioned in GMP certificate)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from NAPROD LIFE SCIENCES PVT. LTD. (304, Town Center-1 Andheri Kurla Road, Andheri , Mumbai.The letter specifies that the manufacturer appoints M/s. Al Habib Pharmaceuticals to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5226 dated: 24-02-2022
	Details of fee submitted	PKR 150,000/- deposit Slip # 47789098702
	The proposed proprietary name / brand name	NAPROCAP Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Capecitabine USP…… 500mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic (Colorectal) WHO ATC code: (L01BC06) (capecitabine) is a nucleoside metabolic inhibitor with antineoplastic activity indicated for:

		• Adjuvant Colon Cancer – Patients with Dukes' C colon cancer. • Metastatic Colorectal Cancer– First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred • Metastatic Breast Cancer– In combination with docetaxel after failure of prior anthracyclinecontaining therapy – As monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XELODA® 500mg of USFDA approved.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	Mac- Chem Products (India) Pvt. Ltd. N-211/2/10. MIDC, Boisar, District- Thane, Pin - 401 506, Maharashtra, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months Batches: (CAP0210002, CAP0210001, CAP0210003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against XELODA Tablet 500mg manufactured by Hoffmann-La-Roche Inc. USA by performing quality tests (Identification, Assay, Dissolution, Hardness, Disintegration Time). The firm has submitted CDP with of XELODA Tablet 500mg manufactured by Hoffmann-La-Roche Inc. USA (Reference Drug Product) in in water, Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	PVC film coated with PVDC and printed Aluminium foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months. Batches:(NT1131, NT1132, NT1133)

Remarks of Evaluator:

Previous Decision(M-324): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.

Regarding our email Dated June 6th 2023 about about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.

We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
1.	Capecitabine 500mg TAB	NAPROCAP -500
2.	Methotrexate 2.5mg TAB	ALLTREX
3.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
4.	Leucovorin Calcium inj. 300mg	CAFONATE
5.	Fluorouracil inj. 500mg	FLUONCO
6.	Bicalutamide 50mg TAB	MACABI
7.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Decision: Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email.

Case no. 05 Registration applications of drugs for which stability study data is submitted

Export facilitation:

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-I(EFD). dated 28-02-2023 has informed that M/S The M/s Nabiqasim Industries has achieved benchmark of USD 1433148.8 during fiscal year 2020-2021 and requested for priority consideration of following molecule the (2 molecule) 02 products:.

735.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Preka oral solution 20mg/ml
	Composition	Each ml contains: Pregabalin ……..…20mg
	Diary No. Date of R& I & fee	Dy.No 383 dated 10-09-2015 (Duplicate Dossier) Rs.50,000 /- Dated 10-09-2015 (Copy)
	Pharmacological Group	Anticonvulsant
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	60ml HDPE bottle
	Approval status of product in Reference Regulator Authorities	Lyrica oral solution 20mg/ml(Pregabalin) Manufactured by: Pfizer USA (FDA Approved)
	Me-too status	
	GMP status	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat, INDIA.		
API Lot No.	PG-1021119		
Description of Pack (Container closure system)	50ml HDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,,3,6 (month) Real Time: 0,3,6,9,12,18 (month)		
Batch No.	108DS04	108DS05	108DS06
Batch Size	2.50 Liter	2.50 Liter	2.50 Liter
Manufacturing Date	1-2022	1-2022	1-2022
Date of Initiation	17-01-2022	17-01-2022	17-01-2022
No. of Batches	03		
Date of Submission	14-11-2022 (32614)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Specific dosage form inspection was not conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# PG- 1021119) of API (Pregabalin) from M/s. Atlas Life science limited. Gujarat, INDIA and M/s NABIQASIM INDUSTRIES (PVT) LTD., Karachi are submitted.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term, 36 Months** (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. S-GMP & GLP/24044908) issued by Food & Drug Control Administration Gujrat state India. issued dated:03-04-2024 and valid till 02-04-2026.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 7, and Commercial Invoice # 044 dated: 23-11-2019 cleared by DRAP (Karachi) on 18-12-2019 specifying 150Kg of Pregabalin batch # PG-1021119.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Same excipients used as used by innovator.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Bach size** / **Mfg. Started** 108DS04 / 2.50 Liter / 01-2022 108DS05 / 2.50 Liter / 01-2022 108DS06 / 2.50 Liter / 01-2022
11.	Record of comparative dissolution data (where applicable)	N/A
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

Firm initially applied brand name Preka oral solution 20mg/ml but in stability studies submission they requested for grant of Registration with Brand name Preneu Oral solution 20mg/ml .

Specification of stability studies are BP

S.No	Shortcomings	Reply
1.	• Pack size applied in form 5D is 60ml while in Stability studies is 50ml. Clarify which is actual pack size. • Provide reference of 50ml fill volume while the Label of innovator product available on	• We have pack size of 50ml and have performed stability studies on 50ml bottle pack size. Revised Form 5-D is attached **(No fee submitted for Revise form 5D)** • 50mL filled volume was used in trial batch studies and the container used for trial batch studies is same as of innovator.

	the USFDA website specifies that the product available in 16 fl oz (473 ml) volume size.	• For commercial product we will use same filled volume as of innovator, we are having provision of filling 500mL volume in our facility.
2.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid DML & GMP certificate is submitted.
3.	In analytical testing method of assay for drug substance wavelength is not mentioned.	In analytical testing method of assay for drug substance the wavelength is mentioned under heading Parameters, mention on page no. 10 of monograph is enclosed.
4.	Details of equipment's used in the trial batches manufacturing	Below is list of equipment's used in the manufacturing of trial batches of Preka Oral solution. 1. EZ Stir, Direct driven Stirrer, Model: HS120A 2. SS Container, 5 Liters 3. Filtration Assembly.
5.	Justification is required for selecting the batch size of 2.5liters for manufacturing of trial batches, along with the submission of complete record of no. of bottles manufactured (batch wise) and no of bottles used for analytical testing of trial batches of finished product at different time points of stability studies.	We have selected the batch size of 2.5 liters for manufacturing of trial batches. Each batch of 2.5 liters consists of 50 bottles containing 50mL of oral solution in each bottle. **No details submitted about utilization**
6.	In analytical testing method of assay for drug product wavelength is not mentioned	In drug product testing method, for assay test the wavelength is mentioned under heading Chromatographic condition mention on page no. 4 of monograph is enclosed.
7.	According to the innovator review report stability of innovator drug product has been performed at the ICH alternative storage conditions of 30°C ± 2°C (at 35% relative humidity, ± 5%), justify for not performing the stability of applied drug product at the alternative storage condition as per the ICH guideline since the drug product packaged in HDPE bottles.	• Justification for conducting stability studies of Preka Oral Solution 20mg/mL conducted at ICH Zone IVA condition (Long term: 30°C±2°C/ 65%RH±5% & Accelerated: 40°C±2°C/ 75%RH±5%) while the product packaged in HDPE bottles **(impermeable container**) is as follows: • HDPE container is not a semi-permeable container according to definition mention in Glossary section of ICH Q1A(R2) enclose for Reference, which states that "Containers that allow the passage of solvent, usually water, while preventing solute loss. The mechanism for solvent transport occurs by absorption into one container surface, diffusion through the bulk of the container material, and desorption from the other surface. Transport is driven by a partial-pressure gradient. Examples of semipermeable containers include plastic bags and semi-rigid, low-density polyethylene (LDPE) pouches for large volume parenteral (LVPs), and LDPE ampoules, bottles, and vials." • Similarly, as per "Asean Guideline On stability of Drug Product" (R1) section 4.7.2 (enclose for

		reference) it is stated as: Generally considered moisture-impermeable containers include glass ampoules, aluminum/aluminum blisters, **High Density Polyethylene (HDPE)** or glass bottles fitted with metal or HDPE closures. Sensitivity to moisture or potential for solvent loss is not a concern for drug products packaged in impermeable containers that provide a permanent barrier to passage of moisture or solvent. Thus stability studies for products stored in impermeable containers can be conducted under any controlled or ambient relative humidity condition. On the basis of above cited references we have conducted stability studies according to ICH Zone – IVA condition and stability data represents that product is stable.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee of Rs:7500/-for revision of form 5D.**

736.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ovuline 0.5mg Tablet
	Composition	Each Tablet Contains: Cabergoline USP…0.5mg
	Diary No. Date of R& I & fee	Dy.No 304 dated 25-04-2011 (Duplicate dossier) Rs.15,000 /- Dated 25-04-2011 and Rs.35,000 /- Dated 04-06-2014 (Copy)
	Pharmacological Group	dopamine receptor agonists
	Type of Form	Form 5D
	Finished product Specifications	USP
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Dostinex Tablet 0.5mg by Pfizer USFDA Approved
	Me-too status	
	GMP status	Firm has submitted copy of cGMP dated 28-05-2022 on the basis of evaluation conducted on 27-05-2022.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s TEVA Czech Industries s.r.o Ostravská 305/29, Komárov 747 70 Opava, Czech Republic
API Lot No.	70235000821
Description of Pack (Container closure system)	Amber glass bottle
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH

	Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	542DS01	542DS02	542DS03
Batch Size	4000 tablets	4000 tablets	4000 tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	15-03-2022	15-03-2022	15-03-2022
No. of Batches	03		
Date of Submission	28-09-2022 (27443)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product Sofosbuvir 400mg tablets which was conducted on 26th October , 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COA (Batch No. 70235000821) of API (Cabergoline) from M/s TEVA Czech Industries s.r.o. , Czech Republic and M/s Nabiqasim Industries (Pvt) Ltd. Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (25°C ± 2°C & 60±5%RH) & **long term, 18 Months** (5°C ± 3°C) stability study reports of 03 batches
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. sukls170328/2021) issued by Competent authority of Czech Republic . issued dated:20-10-2021 on the basis of inspection conducted on 23-07-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 7, and Commercial Invoice # NI2102251 dated: 13-12-2021 cleared by DRAP (Karachi) on 31-12-2021 specifying 0.01Kg of Cabergoline batch # 70235000821
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Same excipients used as used by innovator.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches:

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>542DS01</td><td>4000 tablets</td><td>03-2022</td></tr>
<tr><td>542DS02</td><td>4000 tablets</td><td>03-2022</td></tr>
<tr><td>542DS03</td><td>4000 tablets</td><td>03-2023</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Dostinex”. The details are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of NabiQasim</th></tr>
<tr><td>Brand name</td><td>Dostinex tablet 0.5mg of Pfizer Italia SRL, Italy</td><td>Cabergoline Tablet 0.5mg</td></tr>
<tr><td>Batch No.</td><td>EH3096</td><td>542DS01</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
pH 1.2 HCl buffer
pH 4.5 Acetate buffer
pH 6.8 Phosphate buffer
</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR</td></tr>
<tr><td colspan="2">Submit drug substance stability studies till shelf life.</td><td>Firm submitted drug substance stability studies till shelf life.</td></tr>
<tr><td colspan="3">Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.</td></tr>
</table>

Agenda of Evaluator PEC-V

Agenda Item No. 01:
Routine Applications of Human Drugs (Locally Manufactured) applied on Form - 5F.

737.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd

		Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31431: 02-11-2022
	Details of fee submitted	Slip No:970880266249 PKR 30,000/-
	The proposed proprietary name / brand name	Topamate Tablet 25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Topiramate….25mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic;ATC Code: N03AX11
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Topamax Tablet (USFDA Approved)
	For generic drugs (me-too status)	Registration Number:042824 Brand Name: Topeera 25mg Tablet
	Proposed Pack size	3x10s

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5.	Evidence of approval of relevant section from Licensing Division is required.
2.	3.2.S.4.2	The flow rate for assay determination by API manufacturer is not as per USP .Justification is required for change of flow rate from 0.6 ml /min to 1.5 ml/min on the scientific basis.
3.	3.2.S.4.3	The injection volume on chromatograms of method verification is 10µl whereas, in drug substance analytical test method is 20µl.Justification is required for change in injection volume on the basis of scientific rationale.
4.	3.2.P.2.2.1	The pharmaceutical equivalence report is ambiguous it mentions innovator product "Diamox". Furthermore, there are two documents for comparison with RLD .Submit the relevant document.
5.	3.2.P.2.1.2	Justify the excipient ranges included in the batch formula (3.2.P.3.2) as it is a CQA.
6.	3.2.P.4.1	The specifications for excipients shall be provided.
7.	3.2.P.5.1	a) Justification is required for not performing specific tests for sulfamate and sulfate as required by USP. b) Provide detailed specifications instead of mentioning such terminologies "as per USP" and "meets requirements". Provide justification if certain tests are excluded from specification.
8.	3.2.P.5.2	Clarification is required which dissolution USP test you have adopted Test 1, Test 2 or Test 3 and provide dissolution specifications, accordingly.
9.	3.2.P.5.3	The injection volume on chromatograms of method verification is 10µl whereas, in drug product analytical test method is 100µl.Justification is required for change in chromatographic conditions on the basis of scientific rationale.
10.	3.2.P.8.3	Provide the following supporting documents of stability: ✓ Reference of previous approval of applications with stability study data of the firm (if any)

		✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Data of stability batches will be supported by attested respective documents like **chromatograms, COAs** at each time point, as both are missing. ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
11.	3.2.P.8.3	a) The batch number of drug substance mentioned on stability summary data sheets is BB/TOP/B/1600 whereas, COA provided in section 3.2.S.4.4 is of BB/TOP/B/6001. b) The manufacturing and expiry dates mentioned on stability summary data sheets are different then dates as provided in section 3.2.P.8.1.Moreover, stability initiation dates are not provided on stability summary data sheets.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

738.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36508: 15-12-2022
	Details of fee submitted	Slip No:5309817601 PKR 30,000/-
	The proposed proprietary name / brand name	Topamate Tablet 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Topiramate….100mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic; ATC Code: N03AX11
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Topamax Tablet (USFDA Approved)
	For generic drugs (me-too status)	Product Name: Piralep 100mg Tablet Registration No: 114468
	Proposed Pack size	3x10s

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5.	Evidence of approval of relevant section from Licensing Division is required.
2.	3.2.S.4.2	The flow rate for assay determination by API manufacturer is not as per USP .Justification is required for change of flow rate from 0.6 ml /min to 1.5 ml/min on the scientific basis.

3.	3.2.S.4.3	The injection volume on chromatograms of method verification is 10µl whereas, in drug substance analytical test method is 20µl.Justification is required for change in injection volume on the basis of scientific rationale.
4.	3.2.P.2.1.2	Justify the excipient ranges included in the batch formula (3.2.P.3.2) as it is a CQA.
5.	3.2.P.2.2.1	The pharmaceutical equivalence report is ambiguous it mentions innovator product "Diamox". Furthermore, there are two documents for comparison with RLD .Submit the relevant document.
6.	3.2.P.4.1	The specifications for excipients shall be provided.
7.	3.2.P.5.1	c) Justification is required for not performing specific tests for sulfamate and sulfate as required by USP. d) Provide detailed specifications instead of mentioning such terminologies "as per USP" and "meets requirements". Provide justification if certain tests are excluded from specification.
8.	3.2.P.5.2	Clarification is required which dissolution USP test you have adopted Test 1, Test 2 or Test 3 and provide dissolution specifications, accordingly.
9.	3.2.P.5.3	The injection volume on chromatograms of method verification is 10µl whereas, in drug product analytical test method is 100µl.Justification is required for change in chromatographic conditions on the basis of scientific rationale.
10.	3.2.P.8.3	Provide the following supporting documents of stability: ✓ Reference of previous approval of applications with stability study data of the firm (if any) ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Data of stability batches will be supported by attested respective documents like **chromatograms, COAs** at each time point, as both are missing. ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
11.	3.2.P.8.3	c) The batch number of drug substance mentioned on stability summary data sheets is BB/TOP/B/1600 whereas, COA provided in section 3.2.S.4.4 is of BB/TOP/B/6001. d) The manufacturing and expiry dates mentioned on stability summary data sheets are different then dates as provided in section 3.2.P.8.1.Moreover, stability initiation dates are not provided on stability summary data sheets.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

739.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore**
	Name, address of Manufacturing site.	M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32620: 14-11-2022
	Details of fee submitted	Slip No:861661442 PKR 30,000/-

	The proposed proprietary name / brand name	Lipikan Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Atorvastatin as atorvastatin calcium trihydrate…….10mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Registration Number:023620 Brand Name:Lipitor Tablet 10mg
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. b) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. c) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. d) Submit specification of drug substance by drug product manufacturer.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021). b) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. c) Justification is required for performance of LOD instead of water content.
9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Clarification is required for addition of three diluents in the formulation.

		c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.
11.	3.2.P.2.2.1	a) Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
13.	3.2.P.5.1	a) Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.6	Submit COA of primary reference standard.
16.	3.2.P.8.3	a) Submit date of initiation of stability on stability summary data sheets. b) Submit stability summary data sheets as per DRAP CTD guidance document. c) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Provide supporting documents of stability for initial testing. b) Submit justification for not performing system suitability before assay at each time point.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

740.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore**
	Name, address of Manufacturing site.	M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32621: 14-11-2022
	Details of fee submitted	Slip No:9136459420 PKR 30,000/-
	The proposed proprietary name / brand name	Lipikan Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Atorvastatin as atorvastatin calcium trihydrate…….20mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP

	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Product Name: Lipitor Tablet 20mg Registration No: 023621
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. b) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. c) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. d) Submit specification of drug substance by drug product manufacturer.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021). b) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. c) Justification is required for performance of LOD instead of water content.
9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Clarification is required for addition of three diluents in the formulation. c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.
11.	3.2.P.2.2.1	b) Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
13.	3.2.P.5.1	a) Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.

14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.6	Submit COA of primary reference standard.
16.	3.2.P.8.3	a) Submit date of initiation of stability on stability summary data sheets. b) Submit stability summary data sheets as per DRAP CTD guidance document. c) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	c) Provide supporting documents of stability for initial testing. d) Submit justification for not performing system suitability before assay at each time point.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

741.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma,Pvt. Ltd 3 K.M Head Balloki Road Phool Nagar District Kasur-Pakistan**
	Name, address of Manufacturing site.	M/s Citi Pharma,Pvt. Ltd 3 K.M Head Balloki Road Phool Nagar District Kasur-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 194 03-01-2023
	Details of fee submitted	Slip No:6384414645 PKR 30,000/-
	The proposed proprietary name / brand name	Askprol Extra Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains: Paracetamol…325mg Tramadol…37.5mg**
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics ATC Code:N02AJ13
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA Approved(film coated)
	For generic drugs (me-too status)	Registration Number:077129 Brand Name:Tramal Plus Tablet Market Authorisation Holder:The Searle Company Limited
	Proposed Pack size	1x10’s

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	1.5.4	Provide proposed pack size as it varies from section 3.2.P.7.
4.	1.5.15 – 1.5.20	Submit signed undertakings.
5.	1.6.5	Submit valid DML issued by the relevant regulatory authority of country of origin or valid Good Manufacturing Practice (GMP) certificate of the Tramadol Hydrochloride manufacturer issued by relevant regulatory authority of country of origin.
6.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
Tramadol Hydrochloride		
7.	3.2.S.1.1	Provide which isomer of tramadol HCl has been used, as chemical name mentions trans and structural formula is of cis.
8.	3.2.S.4.1 3.2.S.4.2	Submit drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
9.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
10.	3.2.S.4.4	a) Provide results of analysis of relevant batch of drug substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from drug substance manufacture. b) Submit justification for any incomplete analyses of the drug substance by drug product manufacturer. c) The assay limit of drug substance submitted by drug product manufacturer is NLT 90% which is not as per Ph Eur.
	Paracetamol	
11.	3.2.S.4.1	Submit justification for test of related substances that includes: a) impurity K: maximum 50 ppm; b) impurity J: maximum 10 ppm; c) unspecified impurities: for each impurity, maximum0.05 per cent; d) total: maximum 0.2 per cent; e) reporting threshold: 0.03 per cent, except for impurities J and K.
12.	3.2.S.4.2	Submit analytical procedures used for routine testing of the drug substance by drug product manufacturer.
13.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
14.	3.2.S.4.4	Provide results of analysis of relevant batch of drug substance used during product development and stability studies. Moreover, submit justification for any incomplete analyses of the drug substance by drug product manufacturer as per requirements of BP.
15.	3.2.S.4.5	The justification of specifications mentions all the specs are from USP whereas,3.2.S.4.1 mentions BP.
16.	3.2.P.1	a) Clarification is required for use of tramadol instead of Tramadol Hydrochloride. b) Provide function of the components(excipients) with percentage.

17.	3.2.P.2.1.1	Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product.
18.	3.2.P.2.2.1	a) Provide the weight of core and coat tablet in formulation development. Moreover, formulation development does not provide any information about coating material. b) Submit proper results /values instead of mentioning complies in pharmaceutical equivalence report. c) Submit CDP protocol and supporting documents .
19.	3.2.P.3.2	A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis.
20.	3.2.P.3.5	Provide process validation protocol of commercial batches.
21.	3.2.5.1	Provide the details specs. for dissolution whether Test 1 or Test 2 has been adopted. The average weight of tablet in specifications is 400mg whereas, in batch formula is 447.5mg.Justification is required.
22.	3.2.P.5.2	Submit detailed analytical procedures for testing of drug product.
23.	3.2.P.5.3	a) Provide method verification protocol of applied product as provided report is of Askprol Extra 500mg tablet also provide supporting documents. b) The assay method as per USP is on HPLC whereas, method verification is on UV spectrophotometer.
24.	3.2.P.5.4	Submit copies of complete analysis of at least two batches.
25.	3.2.P.5.5	This section mentions "our production doesnot create impurities". Clarification/justification is required whether test of impurities have been performed.
26.	3.2.P.5.6	This section mentions BP whereas, section 3.2.P.5.1 states USP.
27.	3.2.P.6	Submit COA of primary / secondary reference standard including source and lot number.
28.	3.2.P.8	a) The format of stability summary data sheet is not as per guidance documents. b) The stability summary data sheets specs. are not as per 3.2.P.5.1 for appearance, dissolution. c) The assay mentions API paracetamol, caffeine and aspirin. d) Some chromatograms are of cefepime. e) Documents / Data to be provided along with stability study data: ➢ Reference of previous approval of applications with stability study data of the firm (if any). ➢ Approval of API/ DML/GMP certificate of both API manufacturers issued by concerned regulatory authority of country of origin. ➢ Documents for the procurement of tramadol HCl with approval from DRAP (in case of import).

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

742.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Relizon Pharmaceuticals, Company Address: Plot No 118 Sundar Industrial Estate Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals, Company Address: Plot No 118 Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31995 07-11-2022
	Details of fee submitted	Slip No:050864670512 PKR 30,000/-
	The proposed proprietary name / brand name	Trazone Tablet SR 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet Contains:** **Tramadol Hydrochloride…..100mg**
	Pharmacotherapeutic Group of (API)	Analgesic;ATC: N02AX02
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: Tramaway-SR 100mg Tablets Registration No: 075327
	Proposed Pack size	5's,10's,14's,28's,30's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.2	The brand name specifies each SR whereas, section 1.5.2 does not provide any information regarding sustain release.
2.	1.6.5	Submit valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin OR Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
4.	3.2.S.1.1	Provide which isomer of tramadol has been used for formulation of drug product.
5.	3.2.S.4.1 3.2.S.4.2	Submit drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
6.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
7.	3.2.S.4.4	Provide results of analysis of relevant batch of drug substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from drug substance manufacture. Moreover, submit justification for any incomplete analyses of the drug substance by drug product manufacturer.
8.	3.2.P.1	Submit "Description and Composition of the Drug Product" as per DRAP CTD guidance document. The provided documents are not in accordance with data requirements of guidance document.
9.	3.2.P.2	Submit "Components of the Drug Product" as per DRAP CTD guidance document.
10.	3.2.P.3 to 3.2.P.8.3	The application will be further evaluated on submission of section 3.2.P.1 and 3.2.P.2 as per CTD guidance document. There is no data regarding formulation that includes both qualitative and quantitative details of applied drug product on the basis of which application can be assessed further.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

743.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd Company Address: 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34697: 30-11-2022
	Details of fee submitted	Slip No:6621172200 PKR 30,000/-
	The proposed proprietary name / brand name	Epivag Sachet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each sachet contains:** **Vigabatrin….500mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic;ATC Code: N03AG04
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	SABRIL 500 mg, granules for oral solution in sachet-dose ANSM Approved.
	For generic drugs (me-too status)	Registration Number:070474 Brand Name: Vlep Sachet
	Proposed pack size	60 Sachet.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	2.3.R.1.1	The quantity of povidone in BMR is different than mentioned in batch formula 3.2.P.3.2.
3.	3.2.S.1	Submit general information as per DRAP CTD guidance document.
4.	3.2.S.3	Submit characterization as per CTD guidance document providing details of potential for isomerism and identification of stereochemistry, studies performed to identify potential "**polymorphic form"** and particle size distribution of the Drug substance.
5.	3.2.S.4.2	Submit detailed analytical procedures for the testing of drug substance by drug product manufacturer.
6.	3.2.S.4.4	a) Provide results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / Active Pharmaceutical Ingredient manufacture. b) Submit discussion and justification for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).
7.	3.2.P.1 3.2.P.2	Submit description and composition of the drug product as per guidance document addressing all the sub sections.

8.	3.2.P.2.2.1	Submit the details of the product against which Pharmaceutical equivalence has been performed. Moreover, the report does not include all the tests as per USP, submit justification.
9.	3.2.P.2.6	Submit compatibility studies for the dry powder for solution as per the instructions provided in individual label of the drug product.
10.	3.2.P.3.2	Submit batch formula for commercial batches. Also justify the role of povidone as disintegrant in the formulation.
11.	3.2.P.5.1	The specifications does not include the details of impurities (as applicable) as per guidance document.
12.	3.2.P.8.3	a) Submit summary of additional stability studies i.e. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life. b) Submit date of API lot No/batch no., initiation of stability in stability summary data sheets. c) Submit system suitability report of assay for each time point. d) Provide the weight of powder to prepare 2mg/ml concentration solution. e) The peak areas provided in chromatograms are different then peak areas in raw data sheets. f) Provide COAs of drug product at each time point. g) Submit documents for the procurement of API with approval from DRAP (in case of import). h) Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

744.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Labs(Pvt) Ltd, Plot 145, Industrial Triangle, Kahuta Road.**
	Name, address of Manufacturing site.	M/s Bio-Labs(Pvt) Ltd, Plot 145, Industrial Triangle, Kahuta Road.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3133: 02-02-2023
	Details of fee submitted	Slip No:06988949210 PKR 30,000/-
	The proposed proprietary name / brand name	Voricol Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Voriconazole …50mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic ATC Code: N03AX11
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too status)	Registration Number:069764 Brand Name: Vorif Tablet 50mg
	Proposed Pack size	10s

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	a) The quantity of drug substance in drug product should be on "as is" basis instead of anhydrous.
3.	3.2.S.4.2	Provide the specifications of stationary phase for related substances and enantiomeric purity.
4.	3.2.S.4.3	Clarification is required for use of placebo in specificity test of method verification studies of drug substance.
5.	3.2.S.4.4	a) Submit discussion and justification for incomplete analyses of the drug substance, as per BP by Drug Product manufacturer. b) Provide assay of voriconazole on "as is" basis. c) The water content of drug substance manufacturer is 0.12 % whereas, the water content of same batch in COA of drug substance by drug product manufacturer is 0.3%.Justification is required for variation in water content.
6.	3.2.P.1	a) Provide the quantity of API on "as is" basis. b) Submit reference to the quality standards for all components.
7.	3.2.P.2.2.1	a) The quality tests specification for pharmaceutical equivalence should be similar as specified in section 3.2. P.5.1. b) Submit CDP protocol and formula for calculations of release of voriconazole from drug product. c) Submit CDP profile showing the release patterns. d) Justify the release patterns of applied product,as EPAR of voriconazole tablets(mentions comparable dissolution (i.e. >85% within 15 min) for all 3 pH.
8.	3.2.P.3.2	a) Submit batch formula for proposed commercial batch size that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards. b) Provide the quantity of API on "as is" basis.
9.	3.2.P.5.2	a) Provide the volume of dissolution medium. b) Provide the retention time of voriconazole and flow rate ,as specified in JP.
10.	3.2.P.8.3	a) The system suitability has not been performed before assay at each time point. Justification is required. b) Clarification is required for use of placebo in specificity test of method verification studies for drug product. c) The method validation report mentions test of specificity of molnupiravir. d) The retention time of voriconazole is not as per JP i.e. 9 minutes. Justification is required. e) Submit valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

745.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (PVT.) Ltd** **Company Address: 8th Pharma city , 30-km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Aptcure (PVT.) Ltd Company Address: 8th Pharma city , 30-km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5102: 22-02-20223
	Details of fee submitted	Slip No: 332449563405 PKR 30,000/-
	The proposed proprietary name / brand name	Deslora Tablet 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Desloratadine…5mg
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX27
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Product Name:: Deslavid Tablet 5mg Registration No: 041011 Company Name: Martin Dow Limited
	Proposed Pack size	10s

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	a) The batch size in BMR is 1945 tablets whereas, in stability summary datasheet is 1666 tablets. The qty. of coating material in BMR is 12.26 mg whereas, in 3.2.P.1.2 is 10mg.Justification is required. b) The potency adjustment of API has not been done in BMR. Clarification is required.
3.	3.2.S.3.2	Submit list of Drug Substance / API-related impurities and process-related impurities with acceptance limits.
4.	3.2.S.4.1 3.2.S.4.2	Submit reference for drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
5.	3.2.S.4.3	Submit proper report for analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
6.	3.2.S.4.4	a) Provide results of assay as both anhydrous and as is basis. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).
7.	3.2.P.1.1	Submit description of the dosage form as per guidance document.
8.	3.2.P.1.2	a) Justify the batch size of 16 kg as total sum leads to 32kg. b) Submit the container-closure used for the Drug Product.
9.	3.2.P.2	a) Correct the sequence of documents as per DRAP CTD guidance document and resubmit. b) Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product or provide the reference product which has similar formulation.

		c) The test method is not as per USP, justify the pharmaceutical equivalence studies. d) Submit following documents for CDP: ✓ Using the mean dissolution values from both curves at each time interval, calculate the difference factor (f1) and similarity factor (f2) . ✓ One more measurement should be made after 85% dissolution of both the products.
10.	3.2.P.3.2	a) A batch formula for proposed commercial batch size. b) Provide the details of coating material.
11.	3.2.P.5.1	a) The dissolution medium volume and rpm is not as per USP. b) Specifications shall also include the details of impurities
12.	3.2.P.5.2	The analytical method like assay ,content uniformity is not as per USP. Clarification is required.
13.	3.2.P.5.3	Submit method verification as per USP.
14.	3.2.P.5.4	Submit complete analysis of at least two batches.
15.	3.2.P.8.3.	a) The date of clearance of desloratadine is 21-10-21 whereas, the data of manufacturing of batches in BMR is 08-10-21. Justification is required. b) Submit data logger record at long term condition. c) Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing. d) Submit valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. e) Submit dissolution supporting data for stability at each time point.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

746.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals Company Address: Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.**
	Name, address of Manufacturing site.	Weather Folds Pharmaceuticals Company Address: Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35679: 08-12-2022
	Details of fee submitted	Slip No:9368077181 PKR 30,000/-
	The proposed proprietary name / brand name	Rold Tablet 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each orodispersible tablet contains: Desloratadine…5mg
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX27
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: DES-OD 5mg Tablet Registration No: 072947
	Proposed Pack Size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.4.1 3.2.S.4.2	Submit reference for drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
4.	3.2.S.4.3	Submit proper report for analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
5.	3.2.S.4.4	Provide reference of specifications for evaluation of COA's of both drug substance and drug product manufacturer.
6.	3.2.P.2	Provide how your qualitative composition of the formulation is similar to innovator / reference product. Also submit justification for the quantities of excipients used in the formulation as they are CQAs specifically for xanthan gum which as per FDA inactive database exceeds the potency per unit i.e. 0.15mg. The quantities of all APIs should be in line with "Hand Book of Pharmaceutical Excipients".
7.	3.2.P.2.2.1	a) The assay has not been performed for pharmaceutical equivalence studies. b) Provide the details of product against which pharmaceutical equivalence has been performed. c) Provide comparison of dissolution as per test method of USP. d) Submit proper results /values instead of mentioning complies in pharmaceutical equivalence report. e) Submit CDP protocol and supporting documents .
8.	3.2.P.2.4	Submit discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP) .
9.	3.2.P.3.2	a) A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on as per batch basis.
10.	3.2.P.3.3to 3.2.P.8.3	The application will be assessed further on clarification of qualitative and quantitative composition of formulation. Moreover, whether applied product is film coated or uncoated tablets as process validation and critical steps and intermediates mentions step of coating whereas, section 3.2.P.2 does not provide any information about coating material.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32620: 05-01-2023
	Details of fee submitted	Slip No:80436731 PKR 30,000/-
	The proposed proprietary name / brand name	Find Tablet 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride…..60mg.
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
	For generic drugs (me-too status)	Product Name: Fexocare 60mg Tablet Registration No: 062860
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol , report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.
13.	3.2.P.5.4	a) The dissolution specifications are not as per USP. b) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

		✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	a) Submit the BMRs of stability batches F-01, F-02, F-03. (Find 60mg).

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

748.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 607: 06-01-2023
	Details of fee submitted	Slip No: 91211664508 PKR 30,000/-
	The proposed proprietary name / brand name	Find Tablet 120mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Fexofenadine Hydrochloride…..120mg.**
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
	For generic drugs (me-too status)	Product Name: Fexocare 120mg Tablet Registration No: 062861
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.

6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol , report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.
13.	3.2.P.5.4	a) The dissolution specifications are not as per USP. b) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	a) Submit the BMRs of stability batches F-04, F-05, F-06.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

749.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 483: 05-01-2023
	Details of fee submitted	Slip No:79999139063 PKR 30,000/-
	The proposed proprietary name / brand name	Find Tablet 180mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Fexofenadine Hydrochloride…..180mg.**
	Pharmacotherapeutic Group of (API)	Antihistamine;R06AX26

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
	For generic drugs (me-too status)	Product Name: Fexocare 180mg Tablet Registration No: 062862
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol, report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.
13.	3.2.P.5.4	c) The dissolution specifications are not as per USP. d) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	b) Submit the BMRs of stability batches F-07, F-08, F-09.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

750.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32620: 28-11-2022
	Details of fee submitted	Slip No:81430774989 PKR 30,000/-
	The proposed proprietary name / brand name	Fexin Tablet 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Fexofenadine Hydrochloride…..60mg.**
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: Fexocare 60mg Tablet Registration No: 062860
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Provide valid DML.
2.	3.2.S.1	The chemical name and CAS number of drug substance is different than as provided in USP.
3.	3.2.S.4.3	Submit method verification report with supporting data.
4.	3.2.S.4.4	The assay analysis is not as per USP as the method determines both fexofenadine and fexofenadine related compound A.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur) whereas, specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	e) The composition of the drug mentions pharmacopeia reference BP ,whereas section 3.2.S.4.1 mentions USP.
7.	3.2.P.2.2.1	The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. Moreover, the batch formula mentions reference of drug substance as BP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP .Provide which test of dissolution has been used.
12.	3.2.P.5.2	The analytical test method is not as per USP .

13.	3.2.P.5.4	The dissolution specifications are not as per USP.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	Provide details of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) The dissolution results of each unit should be provided separately. b) Provide the formula on the basis of which dissolution has been calculated. c) The system suitability for assay has not been provided.
18.	3.2.R (T07,T08,T09)	a) The quantity of Fexofenadine in BMR is 600mg. Clarification is required. b) In standard manufacturing procedure of tablet core start time and complete time has not been mentioned. c) Provide trail reconciliation sheet.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

751.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.**
	Name, address of Manufacturing site.	Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34292: 28-11-2022
	Details of fee submitted	Slip No:8835481033 PKR 30,000/-
	The proposed proprietary name / brand name	Fexin Tablet 180mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Fexofenadine Hydrochloride…..180mg.**
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: **Fexocare 180mg Tablet** Registration No: **062862**
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Provide valid DML.
2.	3.2.S.1	The chemical name and CAS number of drug substance is different than as provided in USP.
3.	3.2.S.4.3	Submit method verification report with supporting data.
4.	3.2.S.4.4	The assay analysis is not as per USP as the method determines both fexofenadine and fexofenadine related compound A.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur) whereas, specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	f) The composition of the drug mentions pharmacopeia reference BP ,whereas section 3.2.S.4.1 mentions USP.
7.	3.2.P.2.2.1	The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg which is not commercial. The batch formula mentions reference of drug substance as BP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP .Provide which test of dissolution has been used.
12.	3.2.P.5.2	The analytical test method is not as per USP many details have been skipped.
13.	3.2.P.5.4	The dissolution specifications are not as per USP.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.		a) The dissolution results of each unit should be provided separately. b) Provide the formula on the basis of which dissolution has been calculated. c) The areas of 3 months dissolution testing vary from 0 month.Justify. d) System suitability for assay has not been provided. e) There is overwriting in chromatograms by changing 120mg into180mg.
18.	3.2.R (T10,T11,T12)	a) In standard manufacturing procedure of tablet core start time and complete time has not been mentioned. b) Provide trail reconciliation sheet. c) The COA of tablet mentions specs reference as Innovators.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

752.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi**

	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4535: 16-02-2023
	Details of fee submitted	Slip No:7324123640 PKR 30,000/-
	The proposed proprietary name / brand name	Leomide Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Leflunomide…10mg**
	Pharmacotherapeutic Group of (API)	Immunosupressant;L04AK01 Dihydroorotate dehydrogenase (DHODH) inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: **Lefona Tab 10mg** Registration No: **048313**
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	3.2.P.2.1	a) Clarification is required for the use of surfactant in the formulation. b) Justify the use of fumed silicon dioxide instead of colloidal form.
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 5.97 mg. Justification is required.
4.	3.2.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.
5.	3.2.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

753.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s SAMI Pharmaceuticals Pvt. Ltd.** **F-95 Hub River Road S.I.T.E Karachi**
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3928: 10-02-2023
	Details of fee submitted	Slip No:4420698935 PKR 30,000/-
	The proposed proprietary name / brand name	Leomide Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Leflunomide…20mg
	Pharmacotherapeutic Group of (API)	Immunosupressant;L04AK01 Dihydroorotate dehydrogenase (DHODH) inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: **Leflu Tablet 20mg** Registration No: **094328**
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	3.2.P.2.1	a) Clarification is required for the use of surfactant in the formulation. b) Justify the use of fumed silicon dioxide instead of colloidal form.
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 6.401 mg. Justification is required.
4.	3.2.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.
5.	3.2.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

754.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd.** **Company Address: E-178, S.I.T.E., Super Highway Phase-II, Karachi**
	Name, address of Manufacturing site.	M/s Maxitech Pharma (Pvt) Ltd.

		Company Address: E-178, S.I.T.E., Super Highway Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37074: 20-12-2022
	Details of fee submitted	Slip No:646881642 PKR 30,000/-
	The proposed proprietary name / brand name	Oztela Tablet 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Apremilast…30mg**
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants L04AA32
	Reference to Finished product specifications	Innovators Specification
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	(not provided)
	Proposed Pack size	(not provided)

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	1.5.5	Indicate Pharmacological class of the API (drug substance) with proper reference and WHO ATC code for each distinct therapeutic indication.
3.	1.5.6	Mention the reference specifications of the finished product.
4.	1.6	Submit miscellaneous information as per guidance document.
5.	2.3.R.1	Submit production documentation.
6.	3.2.S.4.1 3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.
7.	3.2.S.4.3	Submit analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
8.	3.2.S.4.4	a) Submit results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer.
9.	3.2.P.1.2	a) Justify the use of magnesium stearate as emulsifier in the drug product. b) The innovator mentions qty. of lactose as lactose monohydrate 171 mg whereas , your formulation contains 50mg.The average tablet weight of comparator product is 312mg whereas, your tablet weight as mentioned in specs. is 210mg.Jusification is required.

10.	3.2.P.2.2.1	c) Submit batch number, DOM and DOE of innovator product.
11.	3.2.P.3.5	The quantitative composition in process validation protocol is different than composition as provided in section 3.2.P.1.2.
12.	3.2.P.5.1	a) The standard weight of tablet varies from weight as provided in 3.2.P.1. b) The innovator uses UPLC for the test whereas, you have used HPLC. c) The test of degradation products and microbial limits have not been included.
13.	3.2.P.5.2	Justify the injection volume 50ul w.r.t. column volume.
14.	3.2.P.5.3	a) The detection limit and quantitation limit has not been performed for assay validation. b) Submit method validation for dissolution.
15.	3.2.P.8.3	a) Provide the API lot number in stability summary datasheets. b) The manufacturing date of TR-001 in stability summary data sheet is 08-2020 whereas, in COA as provided in 3.2.P.5.4 is 09-2020. c) The long term stability report mentions packing detail as ALU-ALU strip whereas, rest of the dossier mentions ALU-ALU blister. d) Submit supporting data of stability of initial analysis. e) Submit reference of previous approval of applications with stability study data of the firm (if any). f) Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. g) Submit documents for the procurement of API with approval from DRAP (in case of import). h) Submit compliance record of HPLC software 21CFR & audit trail reports on product testing. i) Submit record of digital data loggers.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

755.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma** **42 Sundar Industrial Estate Raiwind Road Lahore**
	Name, address of Manufacturing site.	M/s News Pharma 42 Sundar Industrial Estate Raiwind Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34817: 01-12-2022
	Details of fee submitted	Slip No:87592199527 PKR 30,000/-
	The proposed proprietary name / brand name	Newphalac Syrup 3.35g/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml syrup contains** **Lactulose..3.35g**
	Pharmacotherapeutic Group of (API)	Osmotically acting laxatives. ATC Code: A06AD11
	Reference to Finished product specifications	BP

	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Product Name: Duphalac Syrup Registration No: 006655
	Proposed Pack size	60ml, 120ml, 400ml.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section..

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.1	Submit fee of import as you have imported lactulose bulk .
2.	2.3.R.1.1	a) Submit the formula used to calculate quantity of lactulose syrup per bottle. b) Provide number of bottles used for in process testing.
3.	3.2.S.4.1 3.2.S.4.2	a) Submit copies of the Drug substance specifications by drug substance manufacturer. Also provide reference for both specifications. b) Submit clarification for applicability of BP monograph of Lactulose solution on Lactulose syrup. c) Submit analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer. d) Provide the specs. of antimicrobial preservative used in the syrup.
4.	3.2.S.4.3	Submit method verification report with supporting data .
5.	3.2.S.4.4	a) Submit results of analysis of relevant batch(es) of Drug substance performed by Drug Product manufacturer used during **product development and stability studies**, along with **Certificate of Analysis (CoA) of the same batch** from Drug Substance / /Active Pharmaceutical Ingredient manufacture. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer.
6.	3.2.S.7.3	a) Provide the batch size ,volume of container. b) Clarify how stability has been conducted on bulk containers.
7.	3.2.P.2.2.1	a) Submit pharmaceutical equivalence including all the tests as per BP.
8.	3.2.P.5.1 3.2.P.5.2	a) The reference of dug product is BP but you have not included all the tests as per BP. b) The analytical test method is also not as per BP. c) Provide the specs. of antimicrobial preservative used in the syrup.
9.	3.2.P.5.3	a) Submit evidence of differential refractometer and Head-space gas chromatography.
10.	3.2.P.5.4	a) Justify the batch size of 100 bottles. b) Justify the honey flavor .
11.	3.2.P.8.3	a) The test method is not as per BP. The stability testing should be conducted as per BP test method. b) Justify the batch size of 100 bottles, it should be sufficient enough to perform complete testing till the claimed shelf life. c) Submit ADC attested commercial invoice. d) Reference of previous approval of applications with stability study data of the firm (if any). e) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

756.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma** **42 Sundar Industrial Estate Raiwind Road Lahore**
	Name, address of Manufacturing site.	M/s News Pharma 42 Sundar Industrial Estate Raiwind Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33134: 18-11-2022
	Details of fee submitted	Slip No:37030433165 PKR 30,000/-
	The proposed proprietary name / brand name	News Trans DS Suspension 80mg,400mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml suspension contains** **Trimethoprim…80mg** **Sulfamethoxazole…..400mg**
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use; J01EE01
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Product Name: Septran DS Suspension Registration No: 008752
	Proposed Pack size	50ml,400ml.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	a) The manufacturing of batches (09-2021) is before the grant of section (11-2021). b) Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	1.5.9	a) Submit evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board.
Trimethoprim		
4.	3.2.S.1.3	Provide polymorphic form of Trimethoprim.
5.	3.2.S.4.1	a) Submit copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.
6.	3.2.S.4.1 3.2.S.4.2	a) Submit copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer. b) Submit evidence of electrometer.
7.	3.2.S.4.3	Submit method verification report with supporting data .

8.	3.2.S.4.4	Clarify whether all the tests of BP for testing of API has been performed by drug product manufacturer if not submit discussion and justification for any incomplete analyses of the drug substance / API by Drug Product manufacturer.
Sulfamethoxazole		
9.	3.2.S.4.1	Submit copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.
10.	3.2.S.4.1 3.2.S.4.2	a) Submit copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer. b) The assay limit of drug product manufacturer is 98.5% -- 101.0% whereas in BP is 99%-101%. Justification is required. c) Submit evidence of loop injector,gas chromatograph and potentiometer.
11.	3.2.4.4	The test of solubility has not been performed by both API and drug product manufacturer. Justification is required.
12.	3.2.S.5	Submit COA of primary / secondary reference standard including source and lot number.
13.	3.2.P.1	a) The applied formulation does not contains ethanol 96 % whereas innovator/reference product contains 17.8 µL of ethanol per 5 ml.Justification is required. b) Justify the quantity of flavours used in the formulation. c) Justify the use of sulfamethoxazole micronized in your formulation.
14.	3.2.P.2	a) Submit compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product. b) Submit preservative test, w/ml and contents of APIs per volume as per BP for pharmaceutical equivalence.
15.	3.2.P.3.2	Submit batch formula for commercial batches.
16.	3.2.P.5.1	Submit specifications for non-compendial excipients i.e. flavors.
17.	3.2.P.5.2	a) Submit the weight of sample and standard, dilution of sample and standard,weight /ml calculation. b) Submit formula for determination of content of APIs, weight in volume.
18.	3.2.P.5.3	Submit supporting data of method verification studies.
19.	3.2.P.5.4	a) Justify the batch size of 100 bottles, on the basis of inprocess control, used in testing and required for analysis at each time point. b) Calculate the content of APIs, weight in volume. c) Clarification is required for not determining amount of preservative in the suspension and microbiological stability.
20.	3.2.P.8.3	a) The applied container is amber PET bottle, but water loss studies have not been performed. Clarification is required. b) Content of preservatives should be determined. c) **Documents / Data to be provided along with stability study data:** ➢ Reference of previous approval of applications with stability study data of the firm (if any). ➢ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ➢ Documents for the procurement of API with approval from DRAP (in case of import). ➢ Data of stability batches will be supported by attested respective documents like spectras, Raw data sheets. ➢ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Agenda Item No. 02:
Short Molecules priority application as per 178th meeting of the Authority:

757.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: WR7-7MN-E5EZ: 12-03-2024
	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	CellCar Tablets 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Carbamazepine….200mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AF01
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	USFDA Approved.(uncoated tablet)
	For generic drugs (me-too status)	Product Name: **Tegral Tablets** Registration No: **021529**
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluator Remarks
1.	1.5.9	Submit evidence of approval of the applied formulation as **"film coated tablets"** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. The application shall be further evaluated on the provision of evidence as film coated tablets.	The CTD and testing documents were according to innovator's specification, claim as uncoated tablet. Mistakenly we put "film coated tablet" instead of uncoated tablet. Hence we did go through our CTD and replaced statement 'film coated" to "Uncoated".	The firm has replaced film coated with uncoated in the entire CTD. The pharmaceutical equivalence, CDP and stability results are same in both the modules.

Decision: The Board deferred the case for submission Module 2 and Module 3 "Drug product part" for revised formulation as per innovator drug product i.e., uncoated tablet along with full fee of registration as per SRO 496(I)/2023 dated 17.04.2023.

758.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: WJU-9LL-A9D9: 12-03-2024
	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	CellCar Tablets 400mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Carbamazepine….400mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AF01
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	USFDA Approved (Extended Release)
	For generic drugs (me-too status)	Product Name: **Tegral Tablets** Registration No: **021529** (Me too is of 200mg)
	Proposed Pack size	50's.

Evaluation by PEC-V:

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluator Remarks
1.	1.5.9	Clarification regarding its formulation/composition whether its immediate release or extended release. The application shall be further evaluated on the provision of aforesaid clarification.	Our product CellCar 400mg Tablet is an Immediate Release.	Submission of the evidence of approval of the applied formulation in 400mg strength as **"immediate release "** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. The application will be further evaluated on the provision of evidence as immediate release tablet in applied strength.

Decision: The Registration Board deferred for submission of evidence of approval of the applied formulation in 400mg strength as "immediate release " in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting.

759.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Q3U-6A3-5NJN: 12-03-2024
	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	EpiCell 500mg Tablets

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Divalproex sodium equivalent to valproic acid…500mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AG01
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	FDA Approved(as enteric coated)
	For generic drugs (me-too status)	Product Name: Epival 250mg Tablet Registration No: 007160 Me too submitted by firm is of 250mg.
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.5.9	Submit clarification regarding formulation/composition whether its immediate release or delayed release. If "**immediate release " submit evidence** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. Moreover, the provided fee challan is of sustain release. The me too and RRA are of delayed release .The application shall be further evaluated on the provision of aforesaid clarification.	Reply Awaited.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

760.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: PXV-UEV-RE59: 12-03-2024
	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	EpiCell 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each sustain release tablet contains: Divalproex sodium equivalent to valproic acid…500mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AG01

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: **Epival 250mg Tablet** Registration No: **007160** (Incorrect me too submitted by the firm).
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluator remarks
1.5.9	Submit clarification regarding formulation/composition whether it is sustain release or delayed release due to variation in composition mentioned in label claim and section 1.5.2. The application shall be further evaluated on the provision of aforesaid clarification.	EpiCell SR 500mg is Sustained Release. In Section 1.5.2 there is a typographical mistake as has been written enteric coat.	The firm has stated that their tablet is sustain release. However, Product development ,formulation development, CDP studies, PV protocol, Specifications including stability mentions enteric coated tablet.

Decision: The Board deferred the case for submission of Module 2 and Module 3 "Drug product part" for sustain release formulation along with full fee of registration as per SRO 496(I)/2023 dated 17.04.2023.

Agenda of Evaluator PEC-XI

Case No. 01; Routine registration applications of Human Drugs on Form 5F

761.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 27903 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- dated 28-09-2022 (Deposit slip#338309749)

	The proposed proprietary name / brand name	**Lefylo 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Leflunomide……..10mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Immunosuppressant; Dihydroorotate dehydrogenase (DHODH) inhibitors WHO ATC Code; L04AK
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ARAVA Film Coated tablets (10mg, 20mg, 100mg) USFDA Approved. Arava 10 mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Legona 10 Tablet by M/s Akson Pharmaceuticals (Reg# 101792)
	Name and address of API manufacturer.	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability

		studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Lefora 10mg tablets. CDP has been performed against a comparator product ***(name not mentioned)*** in Acid media pH 1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8 and water USP. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted method verification studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China		
API Lot No.	M200701		
Description of Pack (Container closure system)	Leflunomide is available as 1x30's tablet further packed in bleechboard box along with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	15-02-2022	15-02-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 dated 25-01-2022 for import of 01kg of Leflunomide in name of M/s Weatherforlds Pharmaceuticals., attested by AD (I&E) DRAP Peshawar dated 25-01-2022
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of application applied for renewal of DML dated 18-09-2018 and 21-09-2023 in Licensing Division DRAP
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of change of section letter dated 05-05-2010 specifying Tablet (General) • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 27-01-2022.
1.6.5	• Submit valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Not submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided. • The submitted COA of working Standards states that it is valid upto 10-01-2013. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the manufacturing date of drug substance is 15-11-2021	• The firm submitted that mistakenly that COA was submitted. The firm has submitted COA of primary / secondary reference having validity upto 21-08-2023
3.2.P.2	• Manufacturer details of comparator product against which pharmaceutical equivalence studies is performed shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing date, expiry date against which CDP studies is performed shall be submitted	• Firm has submitted details of comparator product Name of product: Lefora 10mg tablet Manufacturer: M/s Hilton Pharma Batch No#142298 Mfg date: 02-2022 Exp date: 02-2025 • The firm submitted that assay test was mistakenly not added and revised

	• Results of assay test are not reported in pharmaceutical equivalence studies • The results of content uniformity test are not reported as per the recommendations of USP <905> (reported as 98.41% for applied product and 100.25% for reference product in pharmaceutical equivalence studies)	pharmaceutical equivalence report is submitted • Content uniformity test results were included
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units (content uniformity) in finished product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided. • Justification shall be submitted for not performing the test for uniformity of dosage units (content uniformity) in batch analysis of finished product as per USP monograph	• The firm has revised finished product specifications in which test for uniformity of dosage units (content uniformity) has been included • Detailed analytical procedures used for testing of the drug product is submitted. • The firm submitted that content uniformity test was performed but mistakenly not included in batch analysis and submitted revised batch analysis report
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard is submitted
3.2.P.7	• Details of the container closure systems shall be provided	• Alu alu blister packed in unit carton
3.2.P.8	• Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of form 6 issued dated 25-01-2022 specifying 1Kg Leflunomide. The invoice is issued by AD (I&E) DRAP. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
  - **ii. Fee Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

762.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 27902 dated 03-10-2022
	Details of fee submitted	***Rs.30,000/- dated 28-09-2022 (Deposit slip#158619981133)***
	The proposed proprietary name / brand name	Lefylo 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Leflunomide……..20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Immunosuppressant; Dihydroorotate dehydrogenase (DHODH) inhibitors WHO ATC Code; L04AK
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ARAVA Film Coated tablets (10mg, 20mg, 100mg) USFDA Approved. Arava 20 mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Legona 20 Tablet by M/s Akson Pharmaceuticals (Reg# 101793)
	Name and address of API manufacturer.	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system

		and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Lefora 20mg tablets. CDP has been performed against a comparator product ***(name not mentioned)*** in Acid media pH 1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8 and water USP. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted method verification studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China		
API Lot No.	M200701		
Description of Pack (Container closure system)	Leflunomide is available as 3x10's tablet further packed in bleechboard box along with leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	15-02-2022	15-02-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 dated 25-01-2022 for import of 01kg of Leflunomide in name of M/s Weatherforlds Pharmaceuticals., attested by AD (I&E) DRAP Peshawar dated 25-01-2022
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [xi]:

Section	Observations	Firm's Response
1.1	• Justify the validity of submitted application since the provided fee challan has not been paid as verified from online eDRAP – Portal (Status Expired)	• Firm has submitted fee Rs. 30000/- vide receipt No#81472704448 for applied formulation.
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of application applied for renewal of DML dated 18-09-2018 and 21-09-2023 in Licensing Division DRAP
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of change of section letter dated 05-05-2010 specifying Tablet (General) • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 27-01-2022.
1.6.5	• Submit valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Not submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.

3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided. • The submitted COA of working Standards states that it is valid upto 10-01-2013. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the manufacturing date of drug substance is 15-11-2021	• The firm submitted that mistakenly that COA was submitted. The firm has submitted COA of primary / secondary reference having validity upto 21-08-2023
3.2.P.2	• Manufacturer details of comparator product against which pharmaceutical equivalence studies is performed shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing date, expiry date against which CDP studies is performed shall be submitted • Results of assay test are not reported in pharmaceutical equivalence studies • The results of content uniformity test are not reported as per the recommendations of USP <905> (reported as 97.95% for applied product and 99.32% for reference product)	• Firm has submitted details of comparator product Name of product: Lefora 20mg tablet Manufacturer: M/s Hilton Pharma Batch No#142301 Mfg date: 02-2022 Exp date: 02-2025 • The firm submitted that assay test was mistakenly not added and revised pharmaceutical equivalence report is submitted • Content uniformity test results were included
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units (content uniformity) in finished product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided. • Justification shall be submitted for not performing the test for uniformity of dosage units (content uniformity) in batch analysis of finished product as per USP monograph	• The firm has revised finished product specifications in which test for uniformity of dosage units (content uniformity) has been included • Detailed analytical procedures used for testing of the drug product is submitted. • The firm submitted that content uniformity test was performed but mistakenly not included in batch analysis and submitted revised batch analysis report
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard is submitted
3.2.P.7	• Details of the container closure systems shall be provided	• Alu alu blister packed in unit carton
3.2.P.8	• Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of form 6 issued dated 25-01-2022 specifying 1Kg Leflunomide. The invoice is issued by AD (I&E) DRAP. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted
Decision: Approved.		

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
  - **ii. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

763.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals., Plot # 69/2, Phase-II, Industrial Estate, Hattar, Haripur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 27904 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- dated 28-09-2022 (Deposit slip#35140856918)
	The proposed proprietary name / brand name	Lefylo 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Leflunomide……..100mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Immunosuppressant; Dihydroorotate dehydrogenase (DHODH) inhibitors WHO ATC Code; L04AK
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ARAVA Film Coated tablets (10mg, 20mg, 100mg) USFDA Approved. Leflunomide 100 mg film-coated tablets MHRA Approved

	For generic drugs (me-too status)	Legona 100 Tablet by M/s Akson Pharmaceuticals (Reg# 101794)
	Name and address of API manufacturer.	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Lefora 100mg tablets. CDP has been performed against a comparator product ***(name not mentioned)*** in Acid media pH 1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8 and water USP. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted method verification studies including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Changzhou Yabang Pharmaceutical Co., Ltd., No. 6 Liangchang East Road, Jintan City., Jiangsu Province China	

API Lot No.	M200701		
Description of Pack (Container closure system)	Leflunomide is available as 3x10's tablet further packed in bleechboard box along with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	15-02-2022	15-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 dated 25-01-2022 for import of 01kg of Leflunomide in name of M/s Weatherforlds Pharmaceuticals., attested by AD (I&E) DRAP Peshawar dated 25-01-2022
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of application applied for renewal of DML dated 18-09-2018 and 21-09-2023 in Licensing Division DRAP
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of change of section letter dated 05-05-2010 specifying Tablet (General) • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 27-01-2022.
1.6.5	• Submit valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Not submitted

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided. • The submitted COA of working Standards states that it is valid upto 10-01-2013. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the manufacturing date of drug substance is 15-11-2021	• The firm submitted that mistakenly that COA was submitted. The firm has submitted COA of primary / secondary reference having validity upto 21-08-2023
3.2.P.2	• Manufacturer details of comparator product against which pharmaceutical equivalence studies is performed shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing date, expiry date against which CDP studies is performed shall be submitted • Justify the results of dissolution studies in Water USP without use of surfactant in CDP studies as water USP is not the dissolution medium in USP monograph (Water containing 0.6% of polyoxyethylene (23) lauryl ether) • Results of assay test are not reported in pharmaceutical equivalence studies	• Firm has submitted details of comparator product Name of product: Lefora 100mg tablet Manufacturer: M/s Hilton Pharma Batch No#142455 Mfg date: 02-2022 Exp date: 02-2025 • The firm submitted that assay test was mistakenly not added and revised pharmaceutical equivalence report is submitted • Content uniformity test results were included
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided. • Justification shall be submitted for not performing the test for uniformity of dosage units in batch analysis of finished product as per USP monograph	• The firm has revised finished product specifications in which test for uniformity of dosage units (content uniformity) has been included • Detailed analytical procedures used for testing of the drug product is submitted. • The firm submitted that content uniformity test was performed but mistakenly not included in batch analysis and submitted revised batch analysis report
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard is submitted
3.2.P.7	• Details of the container closure systems shall be provided	• Alu alu blister packed in unit carton
3.2.P.8	• The dissolution medium mentioned in stability summary sheet is water which is different than USP monograph (Water	• Firm has submitted copy of form 6 issued dated 25-01-2022 specifying 1Kg

	containing 0.6% of polyoxyethylene (23) lauryl ether) • Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	Leflunomide. The invoice is issued by AD (I&E) DRAP. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
  - **ii. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

764.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 29615 dated 18-10-2022
	Details of fee submitted	Rs.30,000/- dated 17-08-2022 (Deposit slip#6245701768)
	The proposed proprietary name / brand name	**Cetazol 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Acetazolamide……..250mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Carbonic anhydrase inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	3x10’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DIAMOX 250mg Tablets MHRA Approved
	For generic drugs (me-too status)	Getacet Tablets by M/s Getz Pharma (Reg. No#98716)
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Acemox tablets 250mg by M/s Vega Pharmaceuticals Pvt. Ltd. CDP has been performed against a comparator product AZM 250mg tablet by M/s Ethical Laboratories in HCl buffer pH

		1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, India		
API Lot No.	AC183015		
Description of Pack (Container closure system)	Alu-PVC blister packed in a bleach board unit carton 3x10's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	25-05-2021	26-05-2021	27-05-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s CTX Lifesciences Pvt. Ltd., Block No. 251/P, 252/P, 253 TO 255, 256/P, 258/P, 276/P, 277, 278/P, 279 TO 282, 283/P, 284/P, GIDC, City: Sachin, District; Surat – Gujarat state, INDIA issued by Food & Drugs Control Administration Gujarat State India valid upto 29-05-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted copy of Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Acetazolamide 1.6gm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of

		stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
3.2.S.4	• Clarification shall be submitted for not selecting the test for residue on ignition, chloride and sulphate by drug product manufacturer as per drug substance manufacturer specifications and USP monograph
3.2.P.5	• Clarification is required for not mentioning the limits of dissolution test in finished product specifications • Clarification is required for not selecting the test for uniformity of dosage units in finished product specifications as per USP monograph • Analytical method for dissolution test is not submitted • Numerical values of dissolution test shall be mentioned in batch analysis of finished product instead of complies.
3.2.P.8	• Submit commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP • Results of dissolution test are not reported in the submitted stability study • In stability study, chromatograms for standard solutions are not submitted. Furthermore, chromatograms for batch # T01 are submitted only

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

765.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 29616 dated 18-10-2022
	Details of fee submitted	Rs.30,000/- dated 17-08-2022 (Deposit slip#17133961)
	The proposed proprietary name / brand name	**Topamate 50mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Topiramate……..50mg

	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Other antiepileptics
	Reference to Finished product specifications	USP
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Topamax 50mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Topira Tablet 50mg by M/s Nexus Pharma (Reg. No#88307)
	Name and address of API manufacturer.	M/s Beloorbayir Biotech Ltd., 4112, "UTKARSHA", Above Concord Motors, 3rd & 4th Floor, K.R. Road, Banashankari 2nd Stage, Bangalore – 560070, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Topagen tablets 50mg by M/s Reko Pharma. CDP has been performed against a comparator product Topagen 50mg tablet by M/s Reko Pharma in HCl buffer pH 1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Beloorbayir Biotech Ltd., 4112, "UTKARSHA", Above Concord Motors, 3rd & 4th Floor, K.R. Road, Banashankari 2nd Stage, Bangalore – 560070, India		
API Lot No.	BBB/TOP/B/6001		
Description of Pack (Container closure system)	Alu-PVC blister packed in a bleach board unit carton 3x10's.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Beloorbayir Biotech Ltd., No.40-43, Satyamangala Industrial Area Tumkur, India issued by Drugs Control Department Bangalore India valid upto one year from the date of issue (issue date; 03-07-2021).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted copy of Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Topiramate 1.1kgm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets and summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate
3.2.S.4	• Submit evidence for availability of refractive index detector used in assay of drug substance by drug product manufacturer
3.2.P.5	• Clarification is required for not mentioning the time of dissolution test in finished product specifications • Submit evidence for availability of refractive index detector used in assay of drug product by drug product manufacturer • Numerical values of dissolution test and uniformity of dosage units test shall be mentioned in batch analysis of finished product instead of complies.
3.2.P.8	• Submit commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP • The submitted chromatograms shows same values of area reported for all the batches at both real time and accelerated conditions of stability study

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

766.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate issued on 28-05-2022 based on inspection conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Form-5F Dy No. 29745 dated 20-10-2022
	Details of fee submitted	Rs. 30,000/- dated 26-09-2022 (Deposit silp#640186866)
	The proposed proprietary name / brand name	**Nubaquel XR 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release film coated tablet contains: Quetiapine Fumarate USP equivalent to Quetiapine……....50mg
	Pharmaceutical form of applied drug	Extended Release Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Antipsychotics; Diazepines, oxazepines, thiazepines and oxepines.
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SEROQUEL XR (50mg, 150mg, 200mg, 300mg, 400mg) film coated extended-release tablets USFDA approved.
	For generic drugs (me-too status)	Zoph XR Tablet 50mg by M/s AGP Limited, (Reg. No. 98772)
	Name and address of API manufacturer.	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product that is Seroquel XL 50mg tablets by M/s Luye Pharma Ltd (under License from Astrazeneca) UK. CDP has been performed against the same brand that is Seroquel XL 50mg tablets in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and QC release media. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India		
API Lot No.	QTP-4207520		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	397DS01	397DS01	--
Batch Size	5000 tablets	5000 tablets	--
Manufacturing Date	03-2021	03-2021	--
Date of Initiation	13-03-2021	13-03-2021	--
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s ZCL Chemicals Ltd., 3102/B, GIDC Industrial Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India issued by Food & Drugs Control Administration Gujarat State India valid upto 06-07-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice for import of 100Kg of Quetiapine Fumarate

		USP (Batch No# QTP4207520) from M/s ZCL Chemicals Ltd., India in name of M/s Nabiqasim Industries (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 03-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Certificate for HPLC software 21CFR compliance is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification is required for not including test for fumaric acid content in drug substance specification by drug product manufacturer as per drug substance manufacturer	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • As per USP monograph of Quetiapine drug substance, USP not mention to perform fumaric acid content test but as per drug substance manufacturer specifications fumaric acid content test is provided additionally, we have revised our API release specifications which include test for fumaric acid content for QC release.
3.2.P.2	• Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as per USP	• Previously test for uniformity of dosage unit was not performed in pharmaceutical equivalence studies at the time of dossier submission, afterward reference to CTD guidance document and Query received on same point for product "Quetiapine XR Tablet 200mg", We have conducted uniformity of dosage unit test for pharmaceutical equivalence studies for "Quetiapine XR Tablet 50mg" and incorporate results in Pharmaceutical Equivalence Studies Report against reference sample. Updated Pharmaceutical Equivalence report is submitted
3.2.P.8	• Submit audit trail reports on product testing	• Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**

i.	**Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

767.	Name, address of Applicant / Marketing Authorization Holder	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 12-11-2021 based on inspection conducted on 05-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-33/2009-Lic dated 07-02-2014 which specifies Tablet (General) section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 30434 dated 27-10-2022
	Details of fee submitted	PKR 75,000/- Dated 18-10-2022 (Deposit slip#8570422535)
	The proposed proprietary name / brand name	**Naprazole 375mg/20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (Enteric Coated)……..375mg Esomeprazole as Magnesium Trihydrate (Immediate Release)……20mg
	Pharmaceutical form of applied drug	Modified release tablet
	Pharmacotherapeutic Group of (API)	NSAID and proton pump inhibitor WHO ATC code: M01AE52
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimovo 20mg;375mg Tablet USFDA Approved ***Discontinued***
	For generic drugs (me-too status)	Glomov 375/20mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd (Reg#109339)
	Name and address of API manufacturer.	**Naproxen:** M/s Dr. Reddy's Laboratories Limited., INDUSTRIAS QUIMICAS FALCON DE MEXICO S.A DE C.V km 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec Morelos Mexico

		Esomeprazole: M/s Metrochem API Private Limited., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Naproxen:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Esomeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Vimovo 375mg/20mg Tablet by M/s Astrazeneca Sweden. CDP has been performed against the same product Vimovo 375mg/20mg Tablet by M/s Astrazeneca Sweden in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in phosphate buffer are in acceptable range. The values of f2 factor are not calculated for esomeprazole as it is unstable in acidic media and acetate buffer. The values of f2 factor are not calculated for naproxen as it is enteric coated and not tablet ruptured in acidic media and acetate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, system suitability, linearity and range, accuracy, precision, detection limit, quantitation limit and robustness.

STABILITY STUDY DATA			
Manufacturer of API	**Naproxen:** Dr. Reddy's Laboratories Limited., INDUSTRIAS QUIMICAS FALCON DE MEXICO S.A DE C.V km 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec Morelos Mexico **Esomeprazole:** M/s Metrochem API Private Limited., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India		
API Lot No.	Naproxen: ANMA000361 Esomeprazole: ESM/1810426		
Description of Pack (Container closure system)	Alu Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-0120220	TF-0130220	TF-0140220
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	20-02-2020	20-02-2020	20-02-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Esomeprazole:** The firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd.,

		Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India issued by Drugs Control Administration Government of Telangana India valid upto 26/10/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole:** Firm has submitted copy of invoice for import of 35kg Esomeprazole Magnesium powder in name of M/s Hiranis Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 25-10-2018 **Naproxen:** Firm has submitted copy of invoice for import of 175kg Naproxen in name of M/s Hiranis Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 02-12-2019
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of letter applied for renewal of DML in Licensing Division DRAP dated 01-02-2024
1.4	• You have applied for a new drug product while the applied product is a generic drug product, clarify	• The firm submitted that the application submitted as NCE product and fee submitted accordingly was an innocent mistake from our end since the applied formulation falls under generic category, we gravely regret the inconvenience caused
1.5.9	• The submitted evidence of Vimovo 20mg;375mg Tablet approved in USFDA is ***Discontinued.*** Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	• Firm has submitted evidence of applied product in RRA. Naproxen And Esomeprazole Magnesium Eq 20mg Base;375mg delayed Release Tablet, USFDA Approved
1.6.5	• Valid GMP certificate / DML of both the Drug Substance manufacturer of Esomeprazole and Naproxen issued by relevant regulatory authority of country of origin is required	**Esomeprazole:** The firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India issued by Drugs Control Administration Government of Telangana India valid upto 12/07/2026

	• Address of manufacturing site of M/s Dr. Reddy's Laboratories Limited., shall be provided	**Naproxen:** Firm has submitted copy of cGMP certificate of M/s Industrias Químicas Falcon de México, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla, Civac, C.P. Jiutepec, Morelos, México valid upto 12-04-2026. • Address of the manufacturing site of M/s Dr. Reddy's Laboratories limited is as follows: Industrias Químicas Falcon de México, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla, 62578 Jiutepec, Morelos, México. • The firm submitted that Dr. Reddy's Laboratories limited is administrative headquarters and Industrias Quimicas Falcon de Mexico is their manufacturing site. This clarification is mentioned in the 3.2.S.2.1 of DMF. 3.2.S.2.1 of DMF has mentioned that Industrias Quimicas Falcon de Mexico, S.A. **.** de C.V is subsidiary of Dr. Reddy's Laboratories Limited.
3.2.P.2	• Justification shall be submitted for not performing the test for uniformity of dosage unit in pharmaceutical equivalence studies as recommended by innovator product	• The firm has submitted revised pharmaceutical studies in which test for uniformity of dosage unit has been performed.
3.2.P.5	• The dissolution time of naproxen at buffer phase (Q after 45min instead of Q at 60min) of finished product specification is different than that of innovator product review document, clarify • The dissolution parameters i.e. volume and rpm (1000ml and 50rpm instead of 475ml and 75rpm) for naproxen at acid stage is different than that of innovator product review document, clarify • The dissolution parameters i.e. volume, rpm and time (1000ml, 50rpm, 45min instead of 900ml, 75rpm and 60min) for naproxen at buffer stage is different than that of innovator product review document, clarify	• The firm submitted that we have used Q after 45 minutes instead of 60 minutes on the basis of USP dissolution chapter <711>, for delayed release dosage forms • The firm submitted that we have used the dissolution parameter for naproxen at acid and buffer stage as 1000ml,50 rpm on the basis of FDA updated dissolution information as per FDA dissolution database as innovator also approved by FDA. • https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm
3.2.P.6	• COA of primary / secondary reference standard of naproxen including source and lot number shall be provided.	• Firm has submitted COA of primary reference standard of naproxen

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

768.	Name, address of Applicant / Marketing Authorization Holder	M/s Moringa Pharmaceuticals (Pvt.) Ltd., 35-A, Sunder Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Moringa Pharmaceuticals (Pvt.) Ltd., 35-A, Sunder Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 29843 dated 21-10-2022
	Details of fee submitted	Rs.30,000/- dated 12-10-2022 (Deposit slip#281781629768)
	The proposed proprietary name / brand name	**Penamor 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Paracetamol…….500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic drug
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol Tablets 500mg MHRA Approved
	For generic drugs (me-too status)	Panadol tablet 500mg by M/s GSK Pakistan (Reg. No#000817)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Manufacturing unit: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Panadol 500mg tablets by M/s GSK Pharma. CDP has been performed against the product Paracetamo 500mg tablet by M/s GSK Pharma in HCl buffer pH 1.2, Phosphate buffer pH 4.5, Phosphate Buffer pH 6.8.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, linearity and range, system suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited., Manufacturing unit: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00510911/044/2022		
Description of Pack (Container closure system)	Alu-PVC packed in bleached board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PARA01	22PARA02	22PARA03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	16-02-2022	16-02-2022	16-02-2022
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate dated 02-09-2020 of M/s Pharmagen Limited., Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore issued based on inspection conducted on 22-06-2020 valid upto two year from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted copy of delivery note dated 09-02-2022 for 05kg paracetamol powder from M/s Pharmagen Limited in the name of M/s Moringa Pharmaceuticals (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like UV absorption data, Raw data sheets and summary data sheets etc. (pharmacopeial method is UV)
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Valid copy of Drug Manufacturing License (DML) is submitted
1.4	• You have applied for a new drug product while the applied product is a generic drug product, clarify	• The firm submitted that our applied product is generic drug product and submitted revised document
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter of renewal of DML dated 26-10-2023. The letter specifies Tablet section (General). • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 25-08-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of Drug substance manufacturer M/s Pharmagen Ltd., based on inspection dated 18-11-2022.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard is submitted

3.2.P.2	• Justify the use of phosphate buffer pH 4.5 used in CDP studies • A brief information on the pharmaceutical development shall be included. • Relevant information in these section 3.2.P.2.3, 3.2.P.2.4, 3.2.P.2.5, 3.2.P.2.6 shall be provided	• Revised CDP is submitted with study performed in acetate buffer pH 4.5 for comparative dissolution study • Information on the pharmaceutical development is submitted. • Information required in these section is provided
3.2.P.5	• Clarification is required for not mentioning the time of dissolution test in finished product specifications • Results of specificity test are not reported in analytical method verification report • The copies of complete analysis of finished product shall be provided.	• Time for dissolution test is mentioned in finished product specifications. Revised specifications is submitted • Revised method verification report with inclusion of specificity result is submitted • Copies of complete analysis of finished product is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

769.	Name, address of Applicant / Marketing Authorization Holder	M/s Moringa Pharmaceuticals (Pvt.) Ltd., 35-A, Sunder Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Moringa Pharmaceuticals (Pvt.) Ltd., 35-A, Sunder Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 29844 dated 21-10-2022
	Details of fee submitted	Rs.30,000/- dated 12-10-2022 (Deposit slip#04247603)
	The proposed proprietary name / brand name	**Penamor suspension 120mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contains: Paracetamol…….120mg
	Pharmaceutical form of applied drug	Liquid Suspension

	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic drug
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 120mg/5ml Oral Suspension MHRA Approved
	For generic drugs (me-too status)	Febrol Suspension 120mg/5ml by M/s Barrett Hodgson Pakistan (Reg. No#23532)
	Name and address of API manufacturer	M/s Pharmagen Limited., Manufacturing unit: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Calpol suspension by M/s GSK Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Precision, Accuracy, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Pharmagen Limited., Manufacturing unit: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00510911/044/2022		
Description of Pack (Container closure system)	60ml PET labeled Bottle packed in unit carton with leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	17-02-2022	17-02-2022	17-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate dated 02-09-2020 of M/s Pharmagen Limited., Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore issued based on inspection conducted on 22-06-2020 valid upto two year from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted copy of delivery note dated 09-02-2022 for 05kg paracetamol powder from M/s Pharmagen Limited in the name of M/s Moringa Pharmaceuticals (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Chromatograms, Raw data sheets and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Valid copy of Drug Manufacturing License (DML) is submitted
1.4	• You have applied for a new drug product while the applied product is a generic drug product, clarify	• The firm submitted that our applied product is generic drug product and submitted revised document
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of letter of renewal of DML dated 26-10-2023. The

	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	letter specifies Liquid Syrup section (General). • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 25-08-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of Drug substance manufacturer M/s Pharmagen Ltd., based on inspection dated 18-11-2022.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard is submitted
3.2.P.2	• A brief information on the pharmaceutical development shall be included. • Relevant information in these section 3.2.P.2.3, 3.2.P.2.4, 3.2.P.2.5, 3.2.P.2.6 shall be provided	• Information on the pharmaceutical development is submitted. • Information required in these section is added
3.2.P.3	• Description of manufacturing process and process controls shall be provided	• No reply is submitted
3.2.P.5	• Test for identification by TLC technique is not submitted in finished product specifications as per BP monograph • Specification for quantification of 4-aminophenol are not submitted in finished product specifications as per BP monograph • The copies of complete analysis of finished product shall be provided.	• No reply is submitted • No reply is submitted • No reply is submitted

Decision: Deferred for submission of following:

- **Description of manufacturing process and process controls**
- **Test for identification by TLC technique in finished product specifications as per BP monograph**
- **Specification for quantification of 4-aminophenol in finished product specifications as per BP monograph**
- **The copies of complete analysis of finished product.**

770.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 33016 dated 17-11-2022
	Details of fee submitted	Rs.30,000/- dated 08-09-2022 (Deposit slip#408771720)
	The proposed proprietary name / brand name	**Roxaban 2.5mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Rivaroxaban……2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Zonabax 2.5mg Tablet by M/s Horizon Healthcare (Reg# 108120)
	Proposed Pack size	20's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's response
3.2.S.4	• Copies of the Drug substance specifications of Drug substance manufacturer is required. • Clarification is required as the declared drug substance specifications is in-house while monograph for the drug substance is available both in USP and BP • The assay method of drug product manufacturer (isocratic method) is different than drug substance manufacturer (gradient method), clarify • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Submit readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis of the same batch from Drug Substance manufacture.	• Copies of the Drug substance specifications of Drug product manufacturer is submitted instead of drug substance manufacturer • The firm submitted that at the time of Product Development and Stability Studies API was not available in any pharmacopeia. However now Rivaroxaban API is available in BP pharmacopeia, we have revised our Method & Specifications accordingly. Also Analytical Method Verification has been performed and submitted. • As API was not available in Pharmacopoeia at the time of Product Development. The API testing method was developed according to the Article of Brazilian journal. Link is given below and for your reference documents of article are submitted https://www.scielo.br/j/bjps/a/p8RzWwkTsrMRwNGVZTcDdDg/ Now API is available in BP so, we have performed testing as per British Pharmacopoeia and revised method is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Certificate of Analysis of the same batch of drug substance from Drug Substance manufacture is submitted. However, Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product

		development and stability studies is not submitted.
3.2.P.5	• You have applied for in house specification in this section and innovator's specifications in section 1.5.6 while the monograph for the applied product is available both in USP and BP. Clarification is required	• The firm submitted that at the time of Product Development and Stability Studies rivaroxaban tablets were not available in any pharmacopeia. • However now it is available in BP & we have revised our Method of Analysis & Specifications accordingly. Also Analytical Method Verification of Rivaroxaban 2.5mg Tablet is submitted
3.2.P.8	• Raw data sheets of stability testing for applied product is not submitted	• Raw data sheets of stability testing for applied product is not submitted

Decision: Deferred for submission of following:

- **Copies of the Drug substance specifications of Drug substance manufacturer**
- **Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies**
- **Raw data sheets of stability testing for applied product**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

771.	Name, address of Applicant / Marketing Authorization Holder	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Name, address of Manufacturing site.	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 972 dated 11-01-2023
	Details of fee submitted	Rs.30,000/- dated 30-12-2022 (Deposit slip#85044256964)
	The proposed proprietary name / brand name	**Rixaban 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rivaroxaban……..2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Zonabax 2.5mg Tablet by M/s Horizon Healthcare (Reg# 108120)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's response
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15th & 16th-01-2024.

3.2.S.4	• Description of test for identification and solubility test must be mentioned in drug substance specifications instead of writing passes test by drug product manufacturer • Clarification is required as the declared drug substance specifications by drug substance manufacturer is in-house while monograph for the drug substance is available both in USP and BP	• Description of test for identification and solubility test is mentioned and revised specifications for drug substance is submitted by drug product manufacturer • The firm has submitted clarification that the drug substance manufacturer has followed Ph.Eur monograph and in-house validated and stability indicative HPLC method for drug substance by drug substance manufacturer and submitted justification
3.2.P.5	• Clarification is required as you have claimed innovator's specifications is module 1 section 1.5.6 and BP specifications in this section • Justifications shall be submitted for using different column specifications for assay test than that recommended by BP • Justification shall be submitted for selecting the limit of assay test 90-110% in batch analysis of drug product instead of 95-105% as submitted in finished product specifications	• The firm submitted that due to typographical error innovator's specifications mentioned in section 1.5.6. Product comply BP. Specification, and revised form 5-F is submitted • The firm submitted that initially HPLC Column 0.055m x 4.0mm x 3µm as per BP Monograph was not available; therefore, alternate column i.e. 100mm x 4.0mm x 5µm was used. Further Verification was also performed on HPLC Column 100mm x 4.0mm x 5µm. Addition to this, Stability study from 12 months and onwards are performed on the HPLC Column 0.055m x 4.0mm x 3µm as mentioned in BP Monograph and results found satisfactory as per Specification. Revised Product specification also submitted. • The firm has submitted revised batch analysis report in which limits of assay test has been mentioned as per submitted specifications (95-105%)

Decision: Approved with BP specifications

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

772.	Name, address of Applicant / Marketing Authorization Holder	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Name, address of Manufacturing site.	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 973 dated 11-01-2023
	Details of fee submitted	Rs.30,000/- dated 30-12-2022 (Deposit slip#9869642176)
	The proposed proprietary name / brand name	**Rixaban 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rivaroxaban……..10mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Zonabax 10mg Tablet by M/s Horizon Healthcare (Reg# 97359)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's response
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15th & 16th-01-2024.
3.2.S.4	• Description of test for identification and solubility test must be mentioned in drug substance specifications instead of writing passes test by drug product manufacturer • Clarification is required as the declared drug substance specifications by drug substance manufacturer is in-house while monograph for the drug substance is available both in USP and BP	• Description of test for identification and solubility test is mentioned and revised specifications for drug substance is submitted by drug product manufacturer • The firm has submitted clarification that the drug substance manufacturer has followed Ph.Eur monograph and in-house validated and stability indicative HPLC method for drug substance by drug substance manufacturer and submitted justification

3.2.P.5	• Clarification is required as you have claimed innovator's specifications is module 1 section 1.5.6 and BP specifications in this section • Justifications shall be submitted for using different column specifications for assay test than that recommended by BP • Justification shall be submitted for selecting the limit of assay test 90-110% in batch analysis of drug product instead of 95-105% as submitted in finished product specifications	• The firm submitted that due to typographical error innovator's specifications mentioned in section 1.5.6. Product comply BP. Specification, and revised form 5-F is submitted • The firm submitted that initially HPLC Column 0.055m x 4.0mm x 3µm as per BP Monograph was not available; therefore, alternate column i.e. 100mm x 4.0mm x 5µm was used. Further Verification was also performed on HPLC Column 100mm x 4.0mm x 5µm. Addition to this, Stability study from 12 months and onwards are performed on the HPLC Column 0.055m x 4.0mm x 3µm as mentioned in BP Monograph and results found satisfactory as per Specification. Revised Product specification also submitted. • The firm has submitted revised batch analysis report in which limits of assay test has been mentioned as per submitted specifications (95-105%)

Decision: Approved with BP specifications

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

773.	Name, address of Applicant / Marketing Authorization Holder	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Name, address of Manufacturing site.	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 36501 dated 15-12-2022
	Details of fee submitted	Rs.30,000/- dated 08-12-2022 (Deposit slip#7532883548)
	The proposed proprietary name / brand name	**Rixaban 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rivaroxaban……..15mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved

	For generic drugs (me-too status)	Zonabax 15mg Tablet by M/s Horizon Healthcare (Reg# 97360)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's response
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15th & 16th-01-2024.
3.2.S.4	• Description of test for identification and solubility test must be mentioned in drug substance specifications instead of writing passes test by drug product manufacturer • Clarification is required as the declared drug substance specifications by drug substance manufacturer is in-house while monograph for the drug substance is available both in USP and BP	• Description of test for identification and solubility test is mentioned and revised specifications for drug substance is submitted by drug product manufacturer • The firm has submitted clarification that the drug substance manufacturer has followed Ph.Eur monograph and in-house validated and stability indicative HPLC method for drug substance by drug substance manufacturer and submitted justification
3.2.P.5	• Clarification is required as you have claimed innovator's specifications is module 1 section 1.5.6 and BP specifications in this section • Justifications shall be submitted for using different column specifications for assay test than that recommended by BP • Justification shall be submitted for selecting the limit of assay test 90-110% in batch analysis of drug product instead of 95-105% as submitted in finished product specifications	• The firm submitted that due to typographical error innovator's specifications mentioned in section 1.5.6. Product comply BP. Specification, and revised form 5-F is submitted • The firm submitted that initially HPLC Column 0.055m x 4.0mm x 3µm as per BP Monograph was not available; therefore, alternate column i.e. 100mm x 4.0mm x 5µm was used. Further Verification was also performed on HPLC Column 100mm x 4.0mm x 5µm. Addition to this, Stability study from 12 months and onwards are performed on the HPLC Column 0.055m x 4.0mm x 3µm as mentioned in BP Monograph and results found satisfactory as per Specification. Revised Product specification also submitted. • The firm has submitted revised batch analysis report in which limits of assay test has been mentioned as per submitted specifications (95-105%)

Decision: Approved with BP specifications

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

774.	Name, address of Applicant / Marketing Authorization Holder	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan

	Name, address of Manufacturing site.	Martin Dow Marker Limited., 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 974 dated 11-01-2023
	Details of fee submitted	Rs.30,000/- dated 30-12-2022 (Deposit slip#817606441168)
	The proposed proprietary name / brand name	**Rixaban 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rivaroxaban……..20mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Xalia 20mg Tablet by M/s CCL Pharmaceuticals (Reg# 87492)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15th & 16th-01-2024.
3.2.S.4	• Description of test for identification and solubility test must be mentioned in drug substance specifications instead of writing passes test by drug product manufacturer • Clarification is required as the declared drug substance specifications by drug substance manufacturer is in-house while monograph for the drug substance is available both in USP and BP	• Description of test for identification and solubility test is mentioned and revised specifications for drug substance is submitted by drug product manufacturer • The firm has submitted clarification that the drug substance manufacturer has followed Ph.Eur monograph and in-house validated and stability indicative HPLC method for drug substance by drug substance manufacturer and submitted justification

3.2.P.5	• Clarification is required as you have claimed innovator's specifications is module 1 section 1.5.6 and BP specifications in this section • Justifications shall be submitted for using different column specifications for assay test than that recommended by BP • Justification shall be submitted for selecting the limit of assay test 90-110% in batch analysis of drug product instead of 95-105% as submitted in finished product specifications	• The firm submitted that due to typographical error innovator's specifications mentioned in section 1.5.6. Product comply BP. Specification, and revised form 5-F is submitted • The firm submitted that initially HPLC Column 0.055m x 4.0mm x 3µm as per BP Monograph was not available; therefore, alternate column i.e. 100mm x 4.0mm x 5µm was used. Further Verification was also performed on HPLC Column 100mm x 4.0mm x 5µm. Addition to this, Stability study from 12 months and onwards are performed on the HPLC Column 0.055m x 4.0mm x 3µm as mentioned in BP Monograph and results found satisfactory as per Specification. Revised Product specification also submitted. • The firm has submitted revised batch analysis report in which limits of assay test has been mentioned as per submitted specifications (95-105%)

Decision: Approved with BP specifications

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

775.	Name, address of Applicant / Marketing Authorization Holder	M/s Aptcure (Pvt.) Ltd., 8- Pharma City, 30 km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd., 8- Pharma City, 30 km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 33634 dated 22-11-2022
	Details of fee submitted	Rs.30,000/- dated 17-11-2022 (Deposit slip#8424166026)
	The proposed proprietary name / brand name	**Aptipride 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Levosulpiride……50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	•
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer as performed by drug substance manufacturer • Justification shall be submitted for selecting different limit of assay test in batch analysis of drug substance by drug product manufacturer (98.5% to 101.5%) than drug substance manufacturer (98.5% to 101%)	•
3.2.P.2	• Similarity factor shall be calculated in CDP studies as the dissolution of the applied product is less than 85% (Less than 70%) in acetate buffer (pH 4.5) and phosphate buffer (pH 6.8)	•
3.2.P.5	• Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 75rpm,) • The copies of complete analysis of at least two batches shall be provided	•
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.8	• Detailed raw data sheet is not submitted • The submitted COA of stability study does not show the time point and storage conditions of stability study	•

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

776.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 2607 dated 27-01-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#8156471400)
	The proposed proprietary name / brand name	**L-prid 50mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.	•
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies	•
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)	•
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.8	• Chromatograms of stability study for applied product are not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

777.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3926 dated 10-02-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#9818258520)
	The proposed proprietary name / brand name	**L-prid 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levopraid 25mg Tablet AIF Italy Approved
	For generic drugs (me-too status)	Levopaid 25mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99723)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.	•
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies	•
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)	•
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

778.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3126 dated 02-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#90918757972)
	The proposed proprietary name / brand name	**Sulrid 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levopraid 25mg Tablet AIF Italy Approved
	For generic drugs (me-too status)	Levopaid 25mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99723)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	•
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	•
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	•
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications	•

	• Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

779.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3127 dated 02-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#9927068333)
	The proposed proprietary name / brand name	**Sulrid 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	•
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	•
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	•
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	•
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

780.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 4042 dated 13-02-2023
	Details of fee submitted	Rs.30,000/- dated 04-01-2023 (Deposit slip#46931188190)
	The proposed proprietary name / brand name	**Levonab 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Levosulpiride……50mg

	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)
	Proposed Pack size	10's, 20's, 30's, 60's, 100's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response

3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (phosphate buffer pH 6.8, 900ml, apparatus 2, 50rpm,)	• The rationale for selecting the dissolution medium/method is as per the recommendation of USP general chapter <1092>, European Medicine Agency Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action and ICH guidance document for "Dissolution Testing of Immediate Release Solid Oral Dosage Forms."
		• The dissolution characteristics of the drug product developed based on consideration of the pH solubility profile and pKa of the drug substance. The drug permeability or octanol/water partition coefficient measurement may be useful in selecting the dissolution methodology and specifications.
		  • The solubility of Levosulpiride drug product is highly soluble in 0.1 N HCl. pH 4.5 Buffer and pH 6.8 buffer (i.e. very rapid dissolution >85% release observed within 15 minutes) as observe in comparative dissolution profile and also mention in Public Assessment Report Scientific discussion of Levosulpiride Aristo tablet range from Aristo Pharma GmbH in pharmaceutical development section, that Levosulpiride exhibits high solubility in 0.1N HCl, pH 4.5 & pH 6.8 medium (very rapidly dissolving scenario).
		  • Rationale for selecting pH 6.8 media as QC release media is that Levosulpiride is S-enantiomer of Sulpride. Levosulpiride has a pKa value of 8.5 approximately near to sulpride pkA value 9.12 and partition coefficient of sulpride is 0.42.
		  • Sulpride tablet monograph is officially available in JP compendia. 2nd fluid is used as dissolution medium (pH 6.8 Buffer); however, we will adapt the proposed dissolution medium **(0.1N HCl)**

		as QC release media for our applied product Levosulpiride tablet Range on the basis of PAR of Reference product.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

781.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 5681 dated 28-02-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#4189136237)
	The proposed proprietary name / brand name	**Codopa 25+100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Carbidopa……..…25mg Levodopa……..100mg
	Pharmacotherapeutic Group of (API)	Carbidopa….decarboxylase inhibitors Levodopa…..central nervous system agents
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	SINEMET (25/100mg, 10/100mg, 25/250mg) uncoated tablets USFDA Approved
	For generic drugs (me-too status)	Cardop 25/100mg Tablet by M/s Hilton Pharma (Reg.No# 92663)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.5.2	• Revise the label claim as per reference formulation considering the hydrated form in case of carbidopa along with submission of applicable fee.	• The firm has revised the label claim as per reference formulation without submission of applicable fee. The revised label claim is as under: Each Tablet Contains: Carbidopa monohydrate equivalent to anhydrous carbidopa……25mg Levodopa……..100mg
1.5.5	• Indicate Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) with proper reference	• The firm has submitted the Pharmacotherapeutic group of Carbidopa and Levodopa i.e. ATC: N04B DOPAMINERGIC AGENTS with reference.

1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of Drug product License (license#ZHe20060667) of API manufacturer issued by Zhejiang Drug Administration valid upto 20-09-2025 • Firm has also submitted copy of cGMP certificate of API manufacturer issued by Zhejiang Medicine Health Administration valid upto 24-10-2026
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa is submitted.
3.2.S.7	• Stability study data of carbidopa and levodopa at zone VI-A conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions. • We submitted the stability data of Carbidopa and Levodopa as per zone IV-B conditions till the claim shelf life in accordance with the WHO Technical Report Series, No. 1010, 2018-Annex 10 which states that "Regulatory authorities in the ICH regions have agreed that the use of more stringent humidity conditions such as 30°C/75% RH will be acceptable".
3.2.P.5	• The concentration of levodopa in standard solution in assay method is less than that recommended in pharmacopeia and sample solution • Results of accuracy test are not submitted in analytical method verification studies	• The firm submitted that we have prepared the sample as per the average weight of the sample by targeting Carbidopa pharmacopoeial concentration, which is 125 mcg/mL, and having a lower label claim as compared to levodopa, which has a higher label claim. As per the target weight of the prepared sample, both actives were analysed in accordance with the USP Pharmacopoeia, which defines nominal or minimal concentrations for both APIs that are not fixed. Moreover we also perform analytical procedure verification which confirms that our procedure is suitable for its intended purposes and the results demonstrate the performance, consistency, and reliability of our analytical procedure. Additionally, we have performed a Linearity Test in analytical procedure verification that includes the Levodopa and Carbidopa concentration levels as per USP pharmacopoeia and also

		established that the results of the Line of Regression (R2) are satisfactory. • In analytical method verification studies results of accuracy test are submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of hydrated form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

782.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 5256 dated 23-02-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#4372487493)
	The proposed proprietary name / brand name	**Codopa 25+250 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Carbidopa equivalent to carbidopa……..…25mg Levodopa……..250mg
	Pharmacotherapeutic Group of (API)	Carbidopa….decarboxylase inhibitors Levodopa…..central nervous system agents
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	SINEMET (25/100mg, 10/100mg, 25/250mg) uncoated tablets USFDA Approved
	For generic drugs (me-too status)	Cardop 25/250mg Tablet by M/s Hilton Pharma (Reg.No# 86607)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.5.2	• Revise the label claim as per reference formulation considering the hydrated form in case of carbidopa along with submission of applicable fee.	• The firm has revised the label claim as per reference formulation without submission of applicable fee. The revised label claim is as under: Each Tablet Contains:

		Carbidopa monohydrate equivalent to anhydrous carbidopa……25mg Levodopa……250mg
1.5.5	• Indicate Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) with proper reference	• The firm has submitted the Pharmacotherapeutic group of Carbidopa and Levodopa i.e. ATC: N04B DOPAMINERGIC AGENTS with reference.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of Drug product License (license#ZHe20060667) of API manufacturer issued by Zhejiang Drug Administration valid upto 20-09-2025 • Firm has also submitted copy of cGMP certificate of API manufacturer issued by Zhejiang Medicine Health Administration valid upto 24-10-2026
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa is submitted.
3.2.S.7	• Stability study data of carbidopa and levodopa at zone VI-A conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions. • The firm stated that we submitted the stability data of Carbidopa and Levodopa as per zone IV-B conditions till the claim shelf life in accordance with the WHO Technical Report Series, No. 1010, 2018-Annex 10 which states that "Regulatory authorities in the ICH regions have agreed that the use of more stringent humidity conditions such as 30°C/75% RH will be acceptable".
3.2.P.5	• The concentration of levodopa in standard solution in assay method is less than that recommended in pharmacopeia and sample solution • Results of accuracy test are not submitted in analytical method verification studies	• The firm submitted that we have prepared the sample as per the average weight of the sample by targeting Carbidopa pharmacopoeial concentration, which is 125 mcg/mL, and having a lower label claim as compared to levodopa, which has a higher label claim. As per the target weight of the prepared sample, both actives were analysed in accordance with the USP Pharmacopoeia, which defines nominal or minimal concentrations for both APIs that are not fixed. Moreover we also perform analytical procedure verification which confirms that our procedure is suitable for its intended purposes and the results demonstrate the performance, consistency, and reliability of our analytical

		procedure. Additionally, we have performed a Linearity Test in analytical procedure verification that includes the Levodopa and Carbidopa concentration levels as per USP pharmacopoeia and also established that the results of the Line of Regression (R2) are satisfactory. • In analytical method verification studies results of accuracy test are submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of hydrated form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

783.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3666 dated 08-02-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#80188962)
	The proposed proprietary name / brand name	**Codopa-CR 25+100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Controlled Release Tablet Contains: Carbidopa ……..…25mg Levodopa……..100mg
	Pharmacotherapeutic Group of (API)	Carbidopa….decarboxylase inhibitors Levodopa…..central nervous system agents
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	SINEMET CR 25/100mg extended release tablets USFDA Approved *Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons***
	For generic drugs (me-too status)	Sinemet Extra 25/100mg Tablet by M/s OBS Pakistan (Reg.No#70445)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.5.2	• Revise the label claim as per reference formulation considering the hydrated form in case of carbidopa along with submission of applicable fee.	• The firm has revised the label claim as per reference formulation without submission of applicable fee. The revised label claim is as under: Each Controlled Release Tablet Contains: Carbidopa monohydrate equivalent to anhydrous carbidopa ……25mg Levodopa……..100mg
1.5.5	• Indicate Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) with proper reference	• The firm has submitted the Pharmacotherapeutic group of Carbidopa and Levodopa i.e. ATC: N04B DOPAMINERGIC AGENTS with reference.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of Drug product License (license#ZHe20060667) of API manufacturer issued by Zhejiang Drug Administration valid upto 20-09-2025 • Firm has also submitted copy of cGMP certificate of API manufacturer issued by Zhejiang Medicine Health Administration valid upto 24-10-2026
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa is submitted.
3.2.S.7	• Stability study data of carbidopa and levodopa at zone VI-A conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions. • We submitted the stability data of Carbidopa and Levodopa as per zone IV-B conditions till the claim shelf life in accordance with the WHO Technical Report Series, No. 1010, 2018-Annex 10 which states that "Regulatory authorities in the ICH regions have agreed that the use of more stringent humidity conditions such as 30°C/75% RH will be acceptable".
3.2.P.2	• F2 factor shall be calculated as the dissolution of applied product is less than 70% in acetate buffer pH 4.5 and acidic media pH 1.2 in CDP studies	• Documents for the calculation of f2 factor for Codopa-CR 25+100mg Tablet are submitted and values of f2 factor are in acceptable range.
3.2.P.5	• Results of accuracy test are not submitted in analytical method verification studies	• In analytical method verification studies results of accuracy test are submitted.
3.2.P.8	• Stability study data of applied product at 6th month time point is not submitted	• Stability study data at 6th month time point is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of hydrated form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

784.	Name, address of Applicant / Marketing Authorization Holder	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/1-Phase IV, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/1-Phase IV, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 4381 dated 15-02-2023
	Details of fee submitted	Rs.75,000/- dated 26-01-2023 (Deposit slip#3586840906)
	The proposed proprietary name / brand name	**Silosin 4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Silodosin……..…4mg
	Pharmacotherapeutic Group of (API)	Alpha adrenoreceptor antagonists
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	RAPAFLO (4mg, 8mg) capsules USFDA Approved
	For generic drugs (me-too status)	Silorap Capsule 4mg by M/s Getz Pharma (Reg#107782)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 24&25-05-2023.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Firm has submitted revised batch analysis report in test for residue on ignition and optical isomer

	Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition and optical isomer in batch analysis of drug substance by drug product manufacturer	has been performed in batch analysis of drug substance
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus, rpm, time and limits (0.1N HCl, 500ml, 50rpm and NLT 85% in 15min) • Analytical conditions for dissolution test (HPLC or UV) is not mentioned in submitted analytical method	• The firm submitted that Silodosin is a highly soluble drug substance (BCS –III) based on ICH Q6A, which states that the drug substance should be considered highly soluble if it meets following two conditions: 1. The dissolution profile of all strengths of the dosage form should be rapid i.e. Dissolution >80 % in 15 minutes at pH 1.2 to 6.8. 2. The highest drug product's strength is soluble in 250mL or less of aqueous media over the pH range of 1.2 to 6.8 at 37°C ± 1°C. • As per ICH Q6A, for dosage forms having drug substances falls in above conditions will be considered as highly soluble drugs and do not require development of discriminatory dissolution method / parameters. Generally, a single time point with one medium is acceptable. • Comparative Dissolution Study by Genome the 'Silosin 4mg Capsule' against the Innovator Product 'Rapaflo 4mg Capsules' Silodosin release more than 85% in three medium within 15minutes at 50 RPM. Also, the solubility of Silodosin is very high throughout the physiological pH range (1.2 to 6.8). The Highest solubility of Silodosin is found to be in pH 1.2 as compared to solubility in pH 4.5 & 6.8, so we selected dissolution medium having pH 1.2. • In light of above discussion and high solubility of drug substance, discriminatory dissolution parameters are not required for Silodosin Capsule. Therefore, generalized lowest 50 RMP with 500ml medium as selected for release and stability studies of the drug product. • As per Comparative Dissolution Study by Genome the 'Silosin 4mg Capsule" against the Innovator Product 'Rapaflo 4mg Capsules' Silodosin release more than 85% in all medium within 15minutes. Therefore, we selected the time point i.e. 15 minutes for dissolution. • The firm submitted that the Analytical Technique is used for Dissolution by the HPLC with the same Chromatographic Condition provided as per ASSAY.
3.2.P.8	• The submitted chromatograms in stability study does not show the batch number, storage conditions	• The firm submitted as Chromatogram is automatically generated by software, T001, T002, T003 are the batch number and Month 01, 02,03 are the time point of stability studies, while

	and time point of stability testing, clarify	Accelerated storage condition (AC) & Real term storage condition (RT) are mentioned on the stability sheets. Some chromatograms and Stability Sheets of three trails are submitted for kind consideration.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

785.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 1855 dated 19-01-2023
	Details of fee submitted	Rs.30,000/- dated 06-01-2023 (Deposit slip#172458599348)
	The proposed proprietary name / brand name	**Sitamax 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin……..…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) Inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Januvia (25mg, 50mg, 100mg) film coated tablet USFDA Approved
	For generic drugs (me-too status)	Trevia 50mg Tablet by M/s Getz Pharma (Reg# 55436)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of written confirmation for active substance exported to EU of API manufacturer valid upto 17-04-2027 issued by Deputy General Director Liaoning Medical Product Administration China. The certificate states that manufacturing plant complies with the requirement of Chinese Good Manufacturing Practice.

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification for drug product is submitted instead of drug substance. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for Enantiomeric purity in batch analysis of drug substance by drug product manufacturer as per submitted specifications • Submit certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture used during product development and stability studies.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Firm has submitted revised batch analysis report of drug substance in which test for enantiomeric purity has been performed • Certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture is submitted
3.2.P.5	• Justification shall be submitted for not selecting specifications for dissolution test in finished product specifications • Justification shall be submitted for selecting different limit of assay test (90%-110%) in batch analysis of dug product than that submitted in finished product specifications (95%-105%)	• The firm submitted that sitagliptin tablet is pharmacopeial product. In USP Monograph of sitagliptin tablet dissolution test is not mentioned. For reference USP monograph of sitagliptin tablet is submitted • The firm submitted that it is a typographical error in assay limit of drug product i.e., (95%-105%). Revised report is submitted. Fee Rs. 7500/- has been submitted for typographical error vide challan No# 675799922791.
3.2.P.8	• Justify the delay between manufacturing of trial batches (04-2022) and initiation of stability studies (06-2022.). • The submitted commercial invoice and form 6 seems to have been overwritten. The submitted invoice and form 6 needs to be verified from concerned filed office	• The firm submitted that delay occurred due to unavailability of certain chemical reagents needed for testing the finished product while we conducted the testing step by step. Our product was manufactured on April 20, 2022. The assay was performed on May 09, 2022, the uniformity of dosage unit by content uniformity was carried out on June 1, 2022, and the product was placed on stability testing on June 8, 2022.

Decision: Deferred for verification of procurement document of API (commercial invoice and Form 6) from concerned field office DRAP

786.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 34284 dated 28-11-2022
	Details of fee submitted	Rs.30,000/- dated 30-09-2022 (Deposit slip#765328177565)
	The proposed proprietary name / brand name	**Savelo 800mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sevelamer Carbonate……800mg
	Pharmacotherapeutic Group of (API)	Phosphate Binders
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Sevelamer carbonate 800mg film-coated tablets MHRA Approved Renvela 800mg film coated Tablets USFDA Approved
	For generic drugs (me-too status)	Renvela 800mg Tablets by M/s sanofi-aventis Pakistan Limited (Reg#85252)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of application applied for renewal of DML dated 12-04-2022
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Control Administration Gujarat State India valid upto 05-05-2023
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Not submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications shall be submitted • Analytical Method Verification studies including specificity,	• Copies of the Drug substance specifications for drug substance by product manufacturer is submitted. However, analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is not submitted • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications is not submitted • Analytical Method Verification studies for drug substance by drug product manufacturer is submitted

	accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer • Submit certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture used during product development and stability studies.	• No justification is submitted • Certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture is submitted
3.2.P.2	• Pharmaceutical equivalence and CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Renvela 800mg Tablet by M/s Genzyme Ireland ltd. Waterford Ireland • The firm submitted that sevelamer carbonate 800mg tablets dissolution test can't be performed like the conventional film coated tablets. Because this product till now is not available in any official monograph like USP, BP, JP etc. furthermore, the afore said product dissolution in FDA dissolution guidance is mentioned to be done by disintegration method. • So the exemption of the dissolution and comparative dissolution may be granted for the product
3.2.P.5	• Justification shall be submitted for not including the test for loss on drying, uniformity of mass, disintegration, potency, microbial purity, titratable amines, soluble oligomers in finished product specifications as per innovator's product review document • Description of test for identification test in finished product specifications shall be submitted • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for not performing the test for loss on drying, uniformity of mass, disintegration, potency, microbial purity, titratable amines, soluble oligomers in finished in batch analysis of drug product as per innovator's product review document	• The firm submitted that titratable amines and soluble oligomers test is done raw material and these are not required in finished product. • Description of test for identification test in finished product specifications is submitted • Analytical procedure for all the tests given in finished product specifications is submitted • Firm has submitted revised batch analysis report in which test for loss on drying, uniformity of mass, disintegration, potency has been performed. However test for titratable amines and soluble oligomers in finished product batch analysis is not performed and firm submit that titratable amines and soluble oligomers test is done raw material and these are not required in finished product.

3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Justification of applying UV Spectrophotometric method for Assay analysis of applied formulation in stability study instead submitted HPLC method. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of form 6 issued dated 21-10-2021 specifying 03Kg Sevelamer Carbonate. The invoice is issued by AD (I&E) DRAP. • The firm submitted that HPLC method is not applicable for phosphate binding capacity so it is performed on UV. However no UV method has been submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted

Decision: Deferred for submission of following:

- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>**
- **Analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer**
- **Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications**
- **Justification for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer**
- **Justification for not performing the test for microbial purity, titratable amines, soluble oligomers in finished in batch analysis of drug product**
- **Analytical method for applied drug product**

787.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3663 dated 08-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#58109440758)
	The proposed proprietary name / brand name	**Sofovel 400/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sofosbuvir…….400mg Velpatasvir……100mg
	Pharmacotherapeutic Group of (API)	Nucleotide polymerase inhibitors / HCV NS5A replication complex inhibitors.
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	EPCLUSA (400mg/100mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Hilvel 400mg/100mg Tablet by M/s Hilton Pharma (Reg# 86973)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	•
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Sofosbuvir and Velpatasvir by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Sofosbuvir and Velpatasvir shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition, and chiral purity in batch analysis of drug substance sofosbuvir by drug product manufacturer as per drug substance manufacturer • Copies of the Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is required. • Justification shall be submitted for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer	•
3.2.S.7	• Stability study data of velpatasvir at real time conditions till claimed shelf life shall be submitted	•
3.2.P.1	• Description and Composition of the applied Drug Product shall be submitted	•
3.2.P.2	• CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted	•
3.2.P.3.2	• Batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process	•
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test for sofosbuvir by UV method.	•
3.2.P.6	• COA of primary / secondary reference standard of sofosbuvir and velpatasvir including source and lot number shall be provided	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric.	•

	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

788.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd., 44-Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd., 44-Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 21-01-2021 based on inspection conducted on 29-12-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-40/2004-Lic (Vol-I) dated 05-03-2019 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 32470 dated 11-11-2022
	Details of fee submitted	Rs.30,000/- dated 30-08-2022 (Deposit slip#54525068890)
	The proposed proprietary name / brand name	**Omper Insta 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……20mg Sodium Bicarbonate……..1680mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal – Malkajgiri (Dist) – Telangana State, India.

		Sodium Bicarbonate: M/s ICI Pakistan Limited., JXM9+37J, H-13, Islamabad Capital territory, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 60 months. **Sodium Bicarbonate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals.

		CDP has been performed against the same product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	Omeprazole: M/s Metrochem API Private Limited, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal – Malkajgiri (Dist) – Telangana State, India. Sodium Bicarbonate: M/s ICI Pakistan Limited., JXM9+37J, H-13, Islamabad Capital territory, Islamabad		
API Lot No.	Omeprazole Powder: OMP/2102059 Sodium Bicarbonate: 314		
Description of Pack (Container closure system)	White to off white colored, fine free flowing powder visually free from foreign particles filled in aluminium foil sachets packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22AT02	22AT03	22AT04
Batch Size	2000 sachet	2000 sachet	2000 sachet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	20-01-2022	20-01-2022	20-01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Metrochem API Private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal –Malkajgiri (Dist) – Telangana State, India., issued by Drugs Control Administration, Telangana India valid upto 22-04-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Omeprazole: Firm has submitted copy of form 6 for import of 01kg Omeprazole in name of M/s Focus & Rulz Pharmaceutical Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 30-03-2021.

		Firm has submitted copy of commercial invoice for import of 01kg Omeprazole in name of M/s Focus & Rulz Pharmaceutical Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 30-03-2021
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of DML renewal application dated 16-02-2023 applied before expiry of DML (18-06-2023)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 12-05-2023 based on inspection conducted on 12-05-2023.
1.5.6	• You have applied for USP specifications in this section while innovator specifications in section 3.2.P.5.1 of module 3. Clarification is required	• The firm submitted that referencing USP specifications in section 1.6.5 of module I was a typographical error. The firm submitted that actual product specification is innovator's specifications as outlined in section 3.2.P.5.1 of module 3.
1.6.5	• Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd, Unit-IV, Plot No.34B, 40B, & 60B, J.N. Pharma City, Thanam (V), Parawada (M), Visakhapatnam Dist-531021, Andhra Pradesh India., issued by Drugs Control Administration, Governemt of Andhra Pradesh India valid upto 13-11-2023. • The submitted GMP certificate is of different manufacturing site than that given in submitted dossier. • The firm submitted that we have purchased one of API i.e. Sodium Bicarbonate manufactured by ICI Pakistan Ltd., from local market for the purpose of trial batches. Vendor did not provide GMP nor DML. We look forward to your understanding and acceptance of information.

3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer is required. • Justification shall be submitted for selecting USP specifications for sodium bicarbonate by drug product manufacturer instead of BP specifications by drug substance manufacturer • Justification shall be submitted by selecting different limit of assay test of sodium bicarbonate by drug product manufacturer (98-102%) than drug substance manufacturer (99-101%) and USP monograph (99-100.5%) • Justification is required as in specificity test of analytical method verification for sodium bicarbonate, *" peak of interest contain no interference*, is mentioned while method of assay is titration • The manufacturing date mentioned on COA of sodium bicarbonate (batch#314) by drug substance manufacturer is 09/2010 and expiry date is 08/2015. Justification is required whether same drug substance was used in development of drug product or otherwise. • The date of analysis mentioned on COA of sodium bicarbonate (batch#030121-M) by drug product manufacturer is 01-03-2022 while manufacturing of trial batches is 01-2022. Justification is required whether analysis of sodium bicarbonate is performed subsequent to the manufacturing of trial batches	• Copies of the Drug substance analytical procedures for sodium bicarbonate by Drug product manufacturer is submitted instead of Drug substance manufacturer. • The firm submitted that we are using USP specifications for drug substance sodium bicarbonate. It was mistakenly mentioned in COA. We have submitted correct and revised COA. • The firm submitted that we are using assay limits of 99.0%-100.5% according to USP specifications. It was mistakenly mentioned in COA and revised COA is submitted. • The firm submitted that upon careful review, it has come to our attention that there was a typographical error on our part. We have performed Sodium carbonate Assay by Titrimetric method. But we mistakenly mentioned Peak of interest while discussing the method of analysis of sodium carbonate being titration. We have submitted correct and finalized analytical method validation report of sodium bicarbonate. • No justification is submitted • The firm submitted that we have received two lots from manufacturer. Drug manufacturer COA which was attached in the dossier by mistake was of next lot having manufacturing date 01-2022 while we used the previous lot (mfg date 03-03-2020) for trial batches. Corrected certificate of analysis is submitted
3.2.P.2	• Justification is required for including mannitol in formulation which is not included in reference product formulation	• The firm submitted that upon careful review, it has come to our attention that the inclusion of mannitol in the formulation in the referenced section of our submission was an oversight and purely a clerical mistake resulting from an internal working document prepared during the formulation development stage. Said trial batch, unfortunately, was not our finalized formulation but rather an in-house formulation working version that was not intended for further processing. • We acknowledge the importance of aligning our submission with the reference product formulation and appreciate your diligence in bringing this matter to our attention. • To address this concern, we have attached the correct and finalized formulation used for the trial batches,

		which accurately reflects the composition intended for the Omper Insta 20mg sachet. This formulation aligns with the reference product specifications and does not include mannitol as erroneously indicated in our earlier submission.
3.2.P.5	• Results of analytical method validation studies for sodium bicarbonate shall be submitted	• Results of analytical method validation studies for sodium bicarbonate is submitted
3.2.P.8	• The wavelength selected for analysis for omeprazole is 302nm in analytical method while submitted chromatogram shows 305nm, clarify? • Submit documents for the procurement of API (Sodium bicarbonate) with approval from DRAP (in case of import).	• The firm submitted that there was a typographical error in standard analytical procedure where wavelength is given as 302 while in chromatogram there was 305. To rectify this error, we have now corrected and revised the procedure and submitted revised procedure. • The firm informed that Sodium Bicarbonate was purchased locally from ICI Pakistan Ltd, Islamabad and submitted purchased order.

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin**
- **Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer**
- **Full fee of registration Rs. 30,000/- for typographical errors**

789.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd., 44-Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd., 44-Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 21-01-2021 based on inspection conducted on 29-12-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-40/2004-Lic (Vol-I) dated 05-03-2019 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 32474 dated 11-11-2022
	Details of fee submitted	Rs.30,000/- dated 02-09-2022 (Deposit slip#2088775103)
	The proposed proprietary name / brand name	**Omper Insta 40mg Sachet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……40mg Sodium Bicarbonate……..1680mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal – Malkajgiri (Dist) – Telangana State, India. Sodium Bicarbonate: M/s ICI Pakistan Limited., JXM9+37J, H-13, Islamabad Capital territory, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 60 months. **Sodium Bicarbonate:** Firm has submitted stability study data of 3

		batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA

Manufacturer of API	Omeprazole: M/s Metrochem API Private Limited, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal – Malkajgiri (Dist) – Telangana State, India. Sodium Bicarbonate: M/s ICI Pakistan Limited., JXM9+37J, H-13, Islamabad Capital territory, Islamabad		
API Lot No.	Omeprazole Powder: OMP/2102059 Sodium Bicarbonate: 314		
Description of Pack (Container closure system)	White to off white colored, fine free flowing powder visually free from foreign particles filled in aluminium foil sachets packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22AT05	22AT06	22AT07
Batch Size	2000 sachet	2000 sachet	2000 sachet

Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	20-01-2022	20-01-2022	20-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Metrochem API Private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal –Malkajgiri (Dist) – Telangana State, India., issued by Drugs Control Administration, Telangana India valid upto 22-04-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Omeprazole: Firm has submitted copy of form 6 for import of 01kg Omeprazole in name of M/s Focus & Rulz Pharmaceutical Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 30-03-2021. Firm has submitted copy of commercial invoice for import of 01kg Omeprazole in name of M/s Focus & Rulz Pharmaceutical Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 30-03-2021
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of DML renewal application dated 16-02-2023 applied before expiry of DML (18-06-2023)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 12-05-2023 based on inspection conducted on 12-05-2023.
1.5.6	• You have applied for USP specifications in this section while innovator specifications in section 3.2.P.5.1 of module 3. Clarification is required	• The firm submitted that referencing USP specifications in section 1.6.5 of module I was a typographical error. The firm submitted that actual product specification is innovator's specifications as outlined in section 3.2.P.5.1 of module 3.
1.6.5	• Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by	• Firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd, Unit-IV, Plot No.34B, 40B, & 60B, J.N. Pharma City, Thanam (V), Parawada (M),

	relevant regulatory authority of country of origin is required	Visakhapatnam Dist-531021, Andhra Pradesh India., issued by Drugs Control Administration, Governemt of Andhra Pradesh India valid upto 13-11-2023. • The submitted GMP certificate is of different manufacturing site than that given in submitted dossier. • The firm submitted that we have purchased one of API i.e. Sodium Bicarbonate manufactured by ICI Pakistan Ltd., from local market for the purpose of trial batches. Vendor did not provide GMP nor DML. We look forward to your understanding and acceptance of information.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer is required. • Justification shall be submitted for selecting USP specifications for sodium bicarbonate by drug product manufacturer instead of BP specifications by drug substance manufacturer • Justification shall be submitted by selecting different limit of assay test of sodium bicarbonate by drug product manufacturer (98-102%) than drug substance manufacturer (99-101%) and USP monograph (99-100.5%) • Justification is required as in specificity test of analytical method verification for sodium bicarbonate, *" peak of interest contain no interference*, is mentioned while method of assay is titration • The manufacturing date mentioned on COA of sodium bicarbonate by drug substance manufacturer is 09/2010 and expiry date is 08/2015. Justification is required whether same drug substance was used in development of drug product or otherwise. • The date of analysis mentioned on COA of sodium bicarbonate (batch#030121-M) by drug product manufacturer is 01-03-2022 while manufacturing of trial batches is 01-2022. Justification is required whether analysis of sodium bicarbonate is performed subsequent to the manufacturing of trial batches	• Copies of the Drug substance analytical procedures for sodium bicarbonate by Drug product manufacturer is submitted instead of Drug substance manufacturer. • The firm submitted that we are using USP specifications for drug substance sodium bicarbonate. It was mistakenly mentioned in COA. We have submitted correct and revised COA. • The firm submitted that we are using assay limits of 99.0%-100.5% according to USP specifications. It was mistakenly mentioned in COA and revised COA is submitted. • The firm submitted that upon careful review, it has come to our attention that there was a typographical error on our part. We have performed Sodium carbonate Assay by Titrimetric method. But we mistakenly mentioned Peak of interest while discussing the method of analysis of sodium carbonate being titration. We have submitted correct and finalized analytical method validation report of sodium bicarbonate. • No justification is submitted • The firm submitted that we have received two lots from manufacturer. Drug manufacturer COA which was attached in the dossier by mistake was of next lot having manufacturing date 01-2022 while we used the previous lot (mfg date 03-03-2020) for trial batches. Corrected certificate of analysis is submitted
3.2.P.2	• Justification is required for including mannitol in formulation which is not included in reference product formulation	• The firm submitted that upon careful review, it has come to our attention that the inclusion of mannitol in the formulation in the referenced section of our submission was an oversight and purely a clerical mistake resulting from an

		internal working document prepared during the formulation development stage. Said trial batch, unfortunately, was not our finalized formulation but rather an in-house formulation working version that was not intended for further processing. • We acknowledge the importance of aligning our submission with the reference product formulation and appreciate your diligence in bringing this matter to our attention. • To address this concern, we have attached the correct and finalized formulation used for the trial batches, which accurately reflects the composition intended for the Omper Insta 40mg sachet. This formulation aligns with the reference product specifications and does not include mannitol as erroneously indicated in our earlier submission.
3.2.P.5	• Results of analytical method validation studies for sodium bicarbonate shall be submitted	• Results of analytical method validation studies for sodium bicarbonate is submitted
3.2.P.8	• The wavelength selected for analysis for omeprazole is 302nm in analytical method while submitted chromatogram shows 305nm, clarify? • Submit documents for the procurement of API (Sodium bicarbonate) with approval from DRAP (in case of import).	• The firm submitted that there was a typographical error in standard analytical procedure where wavelength is given as 302 while in chromatogram there was 305. To rectify this error, we have now corrected and revised the procedure and submitted revised procedure. • The firm informed that Sodium Bicarbonate was purchased locally from ICI Pakistan Ltd, Islamabad and submitted purchased order.

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin**
- **Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer**
- **Full fee of registration Rs. 30,000/- for typographical errors**

Case No. 02; Registration application of Human drugs with stability study data on Form 5D on export facilitation

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

790.	Name and address of manufacturer / Applicant	M/s Tabros Pharma (Pvt.) Ltd., L-20/B, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lulucon Cream 1% w/w
	Composition	Each gram contains:

		Luliconazole…….10mg		
	Diary No. Date of R& I & fee	Dy. No. 320 dated 27/03/2014; PKR 50,000/- dated 27/03/2014 ***Duplicate Dossier (R&I verified)***		
	Pharmacological Group	Imidazole Anti-Fungal		
	Type of Form	Form-5D		
	Finished product Specifications	Manufacturer's specifications		
	Pack size & Demanded Price	10gm, 30gm, 60gm; As per SRO		
	Approval status of product in Reference Regulatory Authorities	LUZU (luliconazole) Cream, 1% for topical use USFDA Approved.		
	Me-too status (with strength and dosage form)	N/A		
	GMP status	Firm has submitted copy of cGMP certificate dated 15-04-2022 issued based on inspection conducted on 07-04-2022		
STABILITY STUDY DATA				
Manufacturer of API		M/s Maithri Drugs Private Limited. Sy. No. 205, 222 to 226, IDA Bonthapally., Village, Gummadidala Mandal, Sangareddy District 502313, Telangana State India		
API Lot No.		LUZO/A746/3C/23		
Description of Pack (Container closure system)		Lacquered aluminium tube		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TR001/LUL	TR002/LUL	TR003/LUL
Batch Size		200 Tubes	200 Tubes	200 Tubes
Manufacturing Date		01-2022	01-2022	01-2022
Date of Initiation		01-2022	01-2022	01-2022
No. of Batches		03		
Date of Submission		(Dy. No 24627) 31-08-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 297th meeting dated 12th-15th January, 202 decided to approve registration of Baxib 2.5mg Tablets, Baxib 5mg Tablets. Inspection date: 05th January, 2021 The report shows that: • The HPLC software is 21 CFR compliant. • Audit Trail on the testing reports of Baxib tablet are available. • Adequate monitoring and control were available for stability chamber		
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.		
3	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted method used for analysis of API from both API Manufacturer and Finished Product manufacturer		
4	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C /		

		75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months.
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate in the name of M/s Maithri Drugs Private Limited. Sy. No. 205, 222 to 226, IDA Bonthapally., Village, Gummadidala Mandal, Sangareddy District 502313, Telangana State India issued by Drug Control Administration Government of Telangana India valid upto 21-07-2023.
6	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 11-10-2021 for import of 120g of Luliconazole in name of M/s Tabrose Pharma Pvt. Ltd attested by AD (I&E) DRAP Karachi dated 26-10-2021. Firm has also submitted copy of form 6 dated 26-10-2021 for import of 120g of Luliconazole in name of M/s Tabrose Pharma Pvt. Ltd attested by AD (I&E) DRAP Karachi dated 26-10-2021.
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	The firm submitted that they used same excipients in their product as used by innovator product so compatibility study with excipients are not required
10	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: Batch no. / Batch Size / Mfg. Started TR001/LUL / 200 Tubes / 01-2022 TR002/LUL / 200 Tubes / 01-2022 TR003/LUL / 200 Tubes / 01-2022
11	Record of comparative dissolution data (where applicable)	The firm submitted that it is not applicable
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Observations	Response
• Submit differential fee Rs. 25000/- as the applied product is a new drug molecule.	• Firm has submitted differential fee Rs. 25000/- deposit slip#0126697910 for applied product
• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required.	• The firm has submitted copy of cGMP certificate of M/s Maithri Drugs Private Limited. Sy. No. 205, 222 to 226, IDA Bonthapally., Bonthapally Village, Gummadidala Mandal, Sangareddy District 502313, Telangana State India issued by Drug Control Administration Government of Telangana India valid upto 19-06-2025
• Justify the batch size of trial batches against the number of units required for complete	• The firm has submitted complete breakup of samples required for complete testing of drug

testing of drug product during stability study including real time stability study till claimed shelf life	product during stability study including real time stability study till claimed shelf life. A total of 154 packs are required for complete testing of applied drug product during stability study till claimed shelf life

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case No. 03; Registration application of Human drugs on Form 5-F on export facilitation

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 02-06-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

791.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 04-11-2022 issued based on inspection conducted on 03-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.2-5/85-Lic (Vol-II) dated 04-07-2022 specifying Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution- (General) (Second Floor) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 36819 dated 19-12-2022
	Details of fee submitted	Rs.30,000/- dated 28-11-2022 (Deposit slip#3241563540)
	The proposed proprietary name / brand name	**Brimo-B Opthalmic Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Brimonidine Tartrate……..…2mg (0.2% w/v) Brinzolamide……..10mg (1% w/v)
	Pharmaceutical form of applied drug	Eye Drops

	Pharmacotherapeutic Group of (API)	Brimonidine Tartrate; alpha-adrenergic agonist Brinzolamide; Carbonic anhydrase inhibitors
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2.5ml, 5ml, 8ml, 15ml, 20ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SIMBRINZA (brinzolamide and brimonidine tartrate ophthalmic suspension) 1%/0.2%, for topical ophthalmic use USFDA Approved
	For generic drugs (me-too status)	Cobrinzo Eye Drops (Ophthalmic Suspension) by M/s Hudson Pharma (Reg# 110234)
	Name and address of API manufacturer.	**Brinzolamide:** M/s Henan Purui Pharmaceutical Co., Ltd., Yezhuang Bridge, Xihua County, Henan Province, China **Brimonidine Tartrate:** M/s Indoco Remedies Ltd., (KILO LAB). R-92/93, 1st floor, T.T.C., M.I.D.C Thane Belapur Road, Rabale, Navi Mumbai – 400701 Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Brimonidine Tartrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Brinzolamide:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for

		36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product SIMBRINZA Eye Drops Suspension by M/s Novartis Pharmaceuticals UK.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, robustness.

STABILITY STUDY DATA

Manufacturer of API	**Brinzolamide:** M/s Henan Purui Pharmaceutical Co., Ltd., Yezhuang Bridge, Xihua County, Henan Province, China **Brimonidine Tartrate:** M/s Indoco Remedies Ltd., (KILO LAB). R-92/93, 1st floor, T.T.C., M.I.D.C Thane Belapur Road, Rabale, Navi Mumbai – 400701 Maharashtra State, India.		
API Lot No.	Brimonidine Tartrate; PK20BRT007 Brinzolamide; 20210701		
Description of Pack (Container closure system)	Sterile suspension in 5ml LDPE bottle packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SE372C	SE373C	SE374C
Batch Size	1000 ml	1000 ml	1000 ml
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-10-2021	08-10-2021	08-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Brinzolamide:** Firm has submitted copy of cGMP certificate of M/s Henan Purui Pharmaceutical Co., Ltd., Yezhuang Bridge, Xihua County, Henan Province, China issued by Henan Pharmaceutical

		Association valid upto 15-06-2025. **Brimonidine Tartrate:** Firm has submitted copy of cGMP certificate of M/s Indoco Remedies Ltd., (KILO LAB). R-92/93, 1st floor, T.T.C., M.I.D.C Thane Belapur Road, Rabale, Navi Mumbai – 400701 Maharashtra State, India issued by Food and Drug Administration Maharashtra State India valid upto 23-12-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Brinzolamide:** Firm has submitted copy of commercial invoice for import of 125gm **Brinzolamide** in name of M/s Atco Laboratories Ltd., attested by AD (I&E) DRAP Karachi dated 12-08-2021 **Brimonidine Tartrate:** Firm has submitted copy of commercial invoice for import of 0.5kgm **Brimonidine Tartrate** in name of M/s Atco Laboratories Ltd., attested by AD (I&E) DRAP Karachi dated 06-07-2021
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of Drug Manufacturing License (DML) of finished product manufacturer valid till 10th April, 2026.
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 04-11-2022 based on inspection conducted on 03-11-2022.
1.6.5	Valid GMP certificate / DML of Drug Substance manufacturer for Brinzolamide and Brimonidine Tartrate issued by relevant regulatory authority of country of origin is required	**Brinzolamide:** Firm has submitted copy of DML No#20150195 of M/s Henan Purui Pharmaceutical Co., Ltd., Yezhuang Bridge, Xihua County, Henan Province, China issued by Food and Drug Administration of Henan Province China valid upto 31-12-2025. **Brimonidine Tartrate:** Firm has submitted copy of cGMP certificate of M/s Indoco Remedies Ltd., (KILO LAB). R-92/93, 1st floor, T.T.C., M.I.D.C Thane Belapur Road, Rabale, Navi Mumbai – 400701 Maharashtra State, India issued by Food and Drug Administration Maharashtra State India valid upto 18-12-2025.

3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance Brimonidine Tartrate and Brinzolamide by Drug product manufacturer is required. • Justification shall be submitted for not including the test for residue on ignition and loss on drying in drug substance specifications (Brinzolamide) by drug substance manufacturer as per USP monograph	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance Brimonidine Tartrate and Brinzolamide by Drug product manufacturer is submitted. • The test for residue on ignition and loss on drying in drug substance (DS) specifications (Brinzolamide) by drug substance manufacturer as per USP monograph in DMF relevant section has been added. The updated Drug Substance Specification is submitted.
3.2.S.5	• COA of primary / secondary reference standard for Brinzolamide including source and lot number shall be provided.	• COA of primary reference standard for Brinzolamide including source and lot number is submitted.
3.2.P.5	• Justification shall be submitted for not including the test for benzalkonium chloride identification, boric acid identification, boric acid assay, appearance of suspension, redispersibility and endotoxin content in finished product specifications as per innovator product review document • Justification is required for selecting limit of pH test in finished product specification as 6.0-7.0 instead of 6.5 as per innovator product review document	• The firm submitted that we have updated our specifications as per Innovator's report during routine Updation of specifications and included all the tests as mentioned in specifications of Innovator's review report and same have been adopted for analysis of onward stability batches. Updated specifications are submitted. • Innovator report mentions 6.5 pH as a set point and same pH is adopted during manufacturing of the product while 6.0 – 7.0 is the limit set for release and shelf-life specifications of our product on the basis of trend.
3.2.P.6	• COA of primary / secondary reference standard of Brinzolamide including source and lot number shall be provided.	• COA of secondary reference standard of Brinzolamide including source and lot number is submitted
3.2.P.8	• Justification is required for manufacturing of trial batches before the grant of additional / revised section approval letter • You have not calculated potential water loss during stability study as mentioned in ICH Q1A (R2) (2.2.7.3. for Drug products packaged in semipermeable containers). Justification is required.	• The firm submitted that we are advised for the clarification of manufacturing of batches before the grant of new additional section. This is because we already have approved manufacturing facility for ophthalmic section as per evidence of earlier GMP certificate (certificate No. 160/2020-DRAP(K) issued on 6th November, 2020, valid till 05th November 2022), indicating the satisfactory GMP status of "Eye Drops" manufacturing facility. • This can also be verified through the routine GMP inspection report dated 09/03/2021, clearly indicating the availability of adequate facility for manufacturing of "EYE DROPS" hence, it is justified that we have manufactured our batches in September, 2021 nevertheless the new additional section was approved later in July, 2022. • The firm submitted that determination of permeation coefficient for container closure system of Brimo-B Ophthalmic Suspension was performed as per ICH Q1A(R2) after successful development of formulation. Water

		loss studies protocol and report along with printed weights taken from analytical balance is being submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 04; Registration application of Human drugs on Form 5-F on export facilitation

Deputy Director PR-II/EFD vide letter No.F.1-6/2019-PR-II (EFD) dated 13-09-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2022-2023** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

792.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30th Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30th Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 01-11-2021 issued based on inspection conducted on 14-09-2021
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 12723 dated 23-05-2023
	Details of fee submitted	Rs.30,000/- dated 02-05-2023 (Deposit slip#0923393542)
	The proposed proprietary name / brand name	**Sitagliptin Phosphate Monohydrate + Metformin HCl 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin……50mg Metformin HCl…….500mg
	Pharmaceutical form of applied drug	Film Coated Tablet

	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Inhouse specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JANUMET (50/500mg, 50/1000mg) film-coated tablets, for oral use USFDA Approved
	For generic drugs (me-too status)	Jasitamet 50/500mg Tablet by M/s Jaskan Pharmaceuticals (Reg# 92511)
	Name and address of API manufacturer	**Sitagliptin Phosphate;** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anqing Anhui 246000 China **Metformin HCl;** M/s Auro Laboratories Ltd., K-56, MIDC Tarapur, Bioser, Dist, Thane, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sitagliptin Phosphate;** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. **Metformin HCl;** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition,

		pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Janumet 50/500mg tablets by M/s Merck Sharp & Dohme Limited UK. CDP has been performed against the same product Janumet 50/500mg tablets by M/s Merck Sharp & Dohme Limited UK in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, system suitability.

STABILITY STUDY DATA			
Manufacturer of API	**Sitagliptin Phosphate;** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anqing Anhui 246000 China **Metformin HCl;** M/s Auro Laboratories Ltd., K-56, MIDC Tarapur, Bioser, Dist, Thane, Maharashtra, India		
API Lot No.	**Sitagliptin Phosphate;** 22100601 **Metformin HCl;** 2018PC0633		
Description of Pack (Container closure system)	Alu-alu Blisters of 2x7's packed in a printed carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	HW0112R	HW0212R	HW0312R
Batch Size	100000 Tablets	100000 Tablets	100000 Tablets
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	26-12-2022	26-12-2022	26-12-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin Phosphate;** Firm has submitted copy of written confirmation for active substance exported to EU of M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anqing Anhui 246000 China valid upto 25-04-2025. The certificate states that manufacturing plant complies with the requirement of Chinese Good Manufacturing Practice. **Metformin HCl:** Firm has submitted copy of cGMP certificate of M/s Auro Laboratories Ltd., K-56, MIDC Tarapur, Bioser, Dist, Thane, Maharashtra, India issued by Ministry of Health and Family Welfare India valid upto 07-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin Phosphate;** Firm has submitted copy of clearance certificate dated 14-12-2022 for import of 20kgm Sitagliptin Phosphate in name of M/s Pacific Pharmaceuticals Ltd., **Metformin HCl:** Firm has submitted copy of commercial invoice for import of 1000kg Metformin HCl in name of M/s Pacific Pharmaceuticals Ltd., attested by AD (I&E) DRAP Lahore dated 11-12-2018
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [xi]:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted copy of application submitted for renewal of DML dated 13-07-2020 (DML issue/renewal date 22-07-2015).
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of cGMP certificate of M/s Pacific Pharnaceuticals Limited Lahore specifying Tablet general section.
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer for Sitagliptin Phosphate and Metformin HCl issued by relevant regulatory authority of country of origin is required	**Sitagliptin Phosphate;** Firm has again submitted copy of written confirmation for active substance exported to EU of M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anqing city, Anhui Province 246000 China valid upto 25-04-2025. The certificate states that manufacturing plant complies with the requirement of Chinese Good Manufacturing Practice. **Metformin HCl:**

		Firm has submitted copy of cGMP certificate of M/s Auro Laboratories Ltd., K-56, MIDC Tarapur, Thane 401506, Maharashtra state, India issued by Food and Drug Administration Maharashtra state India valid upto 26-12-2024.
3.2.S.4	• Provide COA of relevant batch of Drug Substance Metformin HCl from Drug substance manufacturer used during product development and stability studies.	• COA of relevant batch of Drug Substance Metformin HCl from Drug substance manufacturer used during product development and stability studies is submitted (Batch#2018MPC0633)
3.2.P.5	• Justification shall be submitted for selecting the value of Q NLT 70.0% in dissolution test in finished product specifications instead of NLT 75.0% (Q) as per the decision of registration Board • Justification shall be submitted for selecting limit of assay test as 90-110% instead of 95-105% as per EMA pubic assessment report	• The firm submitted that since no pharmacopeial monograph was available for applied formulation at the time of development, so we applied general limits of dissolution for immediate release oral solide dosage forms as per the provisions of British pharmacopeia. Our test results are also above 75%. We will change the specifications as per the latest monograph of British Pharmacopeia. • The firm submitted that since no pharmacopeial monograph was available for applied formulation at the time of development, so we applied general limits of assay. Our test results are also above 95%. We will change the specifications as per the latest monograph of British Pharmacopiea
3.2.P.6	• COA of primary / secondary reference standard of Metformin HCl and Sitagliptin phosphate including source and lot number shall be provided.	• COA of primary reference standard of Metformin HCl and Sitagliptin phosphate including source and lot number is submitted.
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Raw data sheets at initial time point of stability testing is not submitted • Submit copy of clearance certificate or commercial invoice for Sitagliptin Phosphate attested by AD (I&E) DRAP. • The batch No# mentioned on the COA of drug substance Sitagliptin Phosphate and Metformin HCl in batch analysis is 22100601 and 2018PC0633 respectively while batch No# of drug substance Sitagliptin Phosphate and Metformin HCl mentioned in BMR is 22041301 and MEF/12051466. Clarification is required • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted	• Stability study data of applied product at 6th month time point is submitted • Raw data sheets at initial time point of stability testing is submitted • Firm has submitted copy of clearance certificate dated 14-12-2022 for import of 20kgm Sitagliptin Phosphate in name of M/s Pacific Pharmaceuticals Ltd., • The firm submitted that it is human error and submitted revised pages of BMR and Drug substance COA's. • Audit trail reports on product testing is submitted

Decision: Approved with innovator's specifications

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 05: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km Adyala Road Rawalpindi.
The Central Licensing Board in its 289th meeting held on 23rd January, 2023 has considered and approved the following revised section in name of M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km Adyala Road Rawalpindi.., under Drug Manufacturing License No. 000333 (Formulation) vide approval letter No. F. 1-18/92-Lic (Vol-III) dated 27th February 2023.

S No.	Section
1	Soft Gelatine Capsule (General)-New

Following applications have been submitted for registration by the firm.

793.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F UM6-1B3-2QYX dated 23-04-2024
	Details of fee submitted	Rs.30,000/- dated 11-11-2023 (Deposit slip#74238026)
	The proposed proprietary name / brand name	Simalvia Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Alverine citrate……..…..60mg Simethicone…….300mg
	Pharmacotherapeutic Group of (API)	Musculotropic Antispasmodics / Antiflatulents
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[XI]:

Section	Observations	Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for both drug substances issued by relevant regulatory authority of country of origin is required	**Simethicone:** Firm has again submitted copy of cGMP certificate of different manufacturing site of API manufacturer issued by Food and Drugs Administration (Maharashtra State) India valid upto 23-11-2024. (Elkay Chemicals Pvt Ltd, Plot No. F-5, Lote MIDC Area., Lote , Tal-Khed, Ratnagiri - 415722 , Dist – Ratnagiri, District: Ratnagiri India) **Alverine citrate** • Firm has again submitted copy of cGMP certificate of API manufacturer issued by Italian Medicine Agency valid upto 2 end 2022
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability	• Submitted

	studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance alverine citrate by Drug Product manufacturer is required. • Copies of the Drug substance specifications of the Drug substance simethicone by Drug substance manufacturer is required. • Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer shall be submitted • Justification shall be submitted for not including the test for silicon dioxide content and defoaming activity in specification of drug substance by drug product manufacturer as per USP monograph	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance alverine citrate by Drug Product manufacturer is submitted. • Copies of the Drug substance specifications of the Drug substance simethicone by Drug substance manufacturer is submitted. • Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer is not submitted • Firm has submitted revised batch analysis report of drug substance simethicone in which test for silicon dioxide content and defoaming activity has been performed
3.2.S.5	• COA of primary / secondary reference standard of alverine citrate including source and lot number shall be provided.	• COA of primary / secondary reference standard of alverine citrate is submitted
3.2.S.7	• Stability study data of simethicone at real time conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions till 18 months only
3.2.P.5	• Analytical method validation study reports for simethicone in drug product shall be submitted.	• Analytical method validation study reports for simethicone in drug product is submitted.
3.2.P.6	• COA of primary / secondary reference standard of simethicone including source and lot number shall be provided	• COA of secondary reference standard of simethicone is submitted. However it mentioned on the COA that it is to be used before 12-10-2012
3.2.P.8	• Submit documents for the procurement of API Simethicone with approval from DRAP (in case of import).	• Firm has submitted copy of clearance certificate issued dated 21-07-2022 specifying 1000kg of Simethicone USP. The clearance certificate is issued by AD (I&E) DRAP.

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for both drug substances issued by relevant regulatory authority of country of origin is required**
- **Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer**
- **Stability study data of simethicone at real time conditions till claimed shelf life**
- **COA of primary / secondary reference standard of simethicone including source and lot number**

Case No. 06: Deferred Registration applications of Human Drugs on form 5F (New sections):

794.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 12101 dated 17-05-2023
	Details of fee submitted	Rs.30,000/- dated 08-03-2023 (Deposit slip#2130984365)
	The proposed proprietary name / brand name	Bril 500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefazolin (as Sodium)……..…...500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 500mg
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SRATOP 0.5g cefazolin (as sodium) 0.5g powder for injection vial TGA Approved
	For generic drugs (me-too status)	Kefzol 500mg Inj of M/s AGP Limited (Reg# 3755)
	Name and address of API manufacturer.	M/s Shandong Lukang Pharmaceutical Co., Ltd., 88 Deyuan Road, High-Tech Zone, Jining City, Shandong Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. (Batches; 2061801001, 2061801002, 2061801003)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Kefzol 500mg Injection m by M/s AGP Limited by performing quality tests (Description, identification, clarity of solution, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Lukang Pharmaceutical Co., Ltd., 88 Deyuan Road, High-Tech Zone, Jining City, Shandong Province, P.R. China		
API Lot No.	2062103004		
Description of Pack (Container closure system)	A white to off white practically odorless, crystalline powder or white to off white solid, filled in glass vial with rubber stopper and aluminium flip off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 , 9, 12, 18 (Months)		
Batch No.	TR-CEP-63	TR-CEP-64	TR-CEP-65
Batch Size	3081 vials	3081 vials	3081 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	11-09-2021	11-09-2021	11-09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Shandong Lukang Pharmaceutical Co., Ltd., No. 88, Xinhua Road, Zoucheng Industrial Park, Zoucheng City, Shandong Province China issued by Shandong Food and Drug Administration China valid upto 08-07-2023. Firm has submitted copy of DML (License#LU20200470) of M/s Shandong Lukang Pharmaceutical Co., Ltd., 88, Deyuan Road, High-tech Zone, Jining, Shandong China issued by Shandong Provincial Drug Administration valid upto 01-09-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 2021G126 dated 28-06-2021 for import of Cefazolin Sodium Sterile 5kg (Batch#2062103004). *However, the invoice is not attested by AD (I&E) field office*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify	•
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	•
3.2.S.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity and particulate matter in finished product specification as per USP monograph • Justification shall be submitted for not performing the test for content uniformity and particulate matter in batch analysis of finished product as per USP monograph	•
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be provided.	•
3.2.P.8	Documents for procurement of API with approval from DRAP shall be submitted	•

Previous Decision (M-330-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response:

Section	Observations	Response
1.6.5	• Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify	Firm has revised details of drug substance manufacturer in form 5-F section 1.6.5 as per the submitted copy of cGMP certificate; M/s Shandong Lukang Pharmaceutical Co., Ltd., No. 88, Xinhua Road, Zoucheng Industrial Park, Zoucheng City, Shandong Province China
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• The firm has submitted the same previously submitted copy of cGMP certificate along with a copy of request letter dated 08-02-2022 made to area FID & Area Assistant Director (I&E) for renewal of cGMP and conduction of inspection.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
3.2.S.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard is not submitted
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity and particulate matter in finished product specification as per USP monograph • Justification shall be submitted for not performing the test for content uniformity and particulate matter in batch analysis of finished product as per USP monograph	• Firm has submitted revised finished product specifications in which test for content uniformity and particulate matter has been incorporated as per USP monograph • Firm has submitted revised COAs with inclusion of test results for content uniformity and particulate matter
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be provided.	• COA of primary / secondary reference standard is not submitted
3.2.P.8	Documents for procurement of API with approval from DRAP shall be submitted	• Firm has submitted copy of invoice No. 2021G126 dated 28-06-2021 for import of 05kg of Cefazolin Sodium Sterile (Batch# 2062103004). *However, the invoice is not attested by AD (I&E) DRAP field office*

Previous Decision (M-331st): Deferred for submission of following:

- COA of primary / secondary reference standard including source and lot number used for testing of drug substance shall be provided.
- COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches of drug product shall be provided.
- Documents for procurement of API with approval from DRAP shall be submitted

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• COA of primary / secondary reference standard including source and lot number used for testing of drug substance shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted
2	• COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches of drug product shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted
3	• Documents for procurement of API with approval from DRAP shall be submitted	• Firm has submitted copy of invoice No. 2021G126 dated 28-06-2021 for import of 05kg of Cefazolin Sodium Sterile (Batch# 2062103004) attested by AD (I&E) DRAP Lahore.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 07: Deferred Registration applications of Human Drugs on form 5F (New sections):

795.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-12-2021 based on inspection conducted on 04-11-2021.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-18/92-Lic (Vol-III) dated 13th January 2022 specifying Oral Dry Powder Suspension (General)-New
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	UBX-W72-2JPB dated 08-01-2024
	Details of fee submitted	Rs.30,000/- dated 19-12-2023 (Slip# 3166615335)
	The proposed proprietary name / brand name	**Erywell 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Erythromycin Ethylsuccinate equivalent to erythromycin……200mg
	Pharmaceutical form of applied drug	Oral Dry Suspension
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	E-MYCIN 200 erythromycin 200mg/5mL (as ethylsuccinate) powder for oral liquid bottle TGA Approved ERY-PED 200 (erythromycin ethylsuccinate) for oral suspension USFDA Approved
	For generic drugs (me-too status)	Erythrocin Granules 200mg by M/s Indus Pharma Pvt. Ltd. (Reg# 000244)
	Name and address of API manufacturer.	M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its

		verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Erythrocin 200mg/5ml dry suspension.
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand		
API Lot No.	EES/M-002/22		
Description of Pack (Container closure system)	White color labeled cardboard box contains labeled amber plastic bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	015NS03	015NS04	015NS05
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation			
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand., issued by Food & Drugs Administration, Ministry of Public Health Thailand. The certificate states that the manufacturing site should be relied upon to reflect the compliance status until 17th June 2022. The GMP certificate is further extended to 17th June 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 13-10-2023 for import of 10kg of Erythromycin USP in name of M/s Shaigan Pharmaceuticals. However the salt and batch No# of API is different than that given in submitted dossier (batch# EB/M-007/23).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Certificate of Compliance of HPLC software 21CFR is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [xi]:

Section	Observations	Firm's response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter addressed to The Additional Director (QA&LT-I) DRAP Islamabad dated 13-10-2023 for issuance of cGMP certificate.
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of cGMP certificate of M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand., issued by Food & Drugs Administration, Ministry of Public Health Thailand. The certificate states that the manufacturing site should be relied upon to reflect the compliance status until 17th June 2022. The GMP certificate is further extended to 17th June 2023.
3.2.S	• Your applied formulation contains the salt form "Erythromycin Ethylsuccinate" while you have submitted data of "Erythromycin stearate" drug substance. Clarification is required for further processing of your application whether same salt form of drug substance was used in applied product or otherwise	• The firm submitted that by mistake wrong module was attached. Erythromycin Ethylsuccinate is used in applied formulation
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted for selecting BP specifications for drug substance by drug substance manufacturer and submitting batch analysis of drug substance as per USP specifications by both drug substance manufacturer and drug product manufacturer	• Submitted • There are no differences in the USP and BP/EP specifications of Erythromycin Ethylsuccinate for all major tests/parameters, including definition, description, solubility, assay, water content, and storage conditions. The drug substance manufacturer has conducted accelerated stability studies in accordance with BP/EP and USP 38. A copy of the studies is submitted. Additionally, the product specification for Erywell 200mg/5mL dry suspension complies with the USP.
3.2.P.2	• Compatibility studies of the Drug Substance with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. **Applied product** | **Ery-Ped 200** Erythromycin Ethyl Succinate | Erythromycin Ethyl Succinate	• The formulation of Erywell 200mg/5mL dry suspension is similar to reference formulation (Erythromycin ethyl succinate Granules for Oral Suspension by Pinewood Laboratories Limited, Ireland.) therefore compatibility studies is not required, comparison of formulations is given in Table#1 **Applied product** | **Erythromycin**

<table>
<tr><td></td><td><table><tr><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow colour, Icing sugar, Caster sugar, Sodium Saccharin</td><td>Caramel, polysorbate, sodium citrate, sucrose, xanthan gum and artificial flavors</td></tr></table></td><td><table><tr><td></td><td>ethyl succinate Granules for Oral Susp.</td></tr><tr><td>Erythromycin Ethyl Succinate</td><td>Erythromycin Ethyl Succinate</td></tr><tr><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow colour, Icing sugar, Caster sugar, Sodium Saccharin</td><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow color, Banana Flavor, Sucrose (Caster sugar), Sodium Saccharin,</td></tr></table>• However, the reference product has a different strength then the applied product. Primacine 250 mg/5 ml Granules for Oral Suspension Ireland approved</td></tr>
<tr><td>3.2.P.5</td><td>• Analytical method for assay test (microbial assay) for applied product is not submitted
• Analytical method verification report for assay test is not submitted</td><td>• Copy of Method of microbial assay for antibiotics is submitted
• Analytical method verification report of assay is submitted</td></tr>
<tr><td>3.2.P.8</td><td>• Date of initiation and implementation is mentioned as 27-12-2023 while manufacturing date of trial batches is mentioned as 12-2022 in stability summary sheets, clarify</td><td>• This is a typographical error in stability sample sheet. The date of initiation of stability was 27-12-2022 which is also mentioned on the stability summary sheets. A revised and updated copy of the stability sample sheet is submitted.</td></tr>
<tr><td></td><td>• Clarification is required since the import date of drug substance as per submitted clearance certificate (13-10-2023) is subsequent to the manufacturing date (12-2022) of trial batches (as per submitted batch analysis report, BMR and stability summary sheets)
• The batch number of API in clearance certificate is different than that given in submitted dossier, clarify</td><td>• By mistake wrong import invoice was attached that’s why there was difference in dates. New invoice is submitted.
• Firm has submitted copy of commercial invoice dated 01-09-2022 for import of 13kg of Erythromycin Ethyl succinate USP (Batch# EES/M-002/22) in name of M/s Shaigan Pharmaceuticals. However invoice is not attested by AD (I&E) DRAP.</td></tr>
<tr><td></td><td>• Raw data sheets including calculation details for assay test is not submitted</td><td>• Raw data sheets including calculation details for assay test is submitted</td></tr>
<tr><td></td><td>• Complete in-use stability study of batch No#015NS03 and 015NS04 shall be submitted</td><td>• In use stability summary sheets submitted</td></tr>
<tr><td></td><td>• Stability summary sheet of batch No#015NS05 at accelerated conditions shall be submitted</td><td>• Not submitted</td></tr>
<tr><td></td><td>• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required</td><td>• Record of digital data logger is submitted</td></tr>
<tr><td colspan="3">Previous Decision (M-335th-DRB): Deferred for submission of following:
• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin
• Compatibility studies of the Drug Substance with excipients as the qualitative composition of the formulation is not similar to innovator / reference product.</td></tr>
</table>

- Clearance certificate or commercial invoice attested by AD (I&E) DRAP
- Stability summary sheet of batch No#015NS05 at accelerated conditions

Firm's Response:

Section	Observations	Firm's response
1	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Firm has submitted copy of cGMP certificate of M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand., issued by Food & Drugs Administration, Ministry of Public Health Thailand. The certificate reflects the status of the manufacturing site at the time of inspection and should not be relied upon to reflect the compliance status until 23rd July 2026.
2	• Compatibility studies of the Drug Substance with excipients as the qualitative composition of the formulation is not similar to innovator / reference product.	• The firm has submitted compatibility studies of the Drug Substance with excipients
3	• Clearance certificate or commercial invoice attested by AD (I&E) DRAP	• Firm has submitted copy of form 6 issued dated 22-07-2022 specifying 13Kg Erythromycin Ethyl Succinate. The invoice is issued by AD (I&E) DRAP.
4	• Stability summary sheet of batch No#015NS05 at accelerated conditions	• Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

796.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17572 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#982634498)
	The proposed proprietary name / brand name	**Vyber 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……20mg Sodium Bicarbonate……..1680mg (as buffer)
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including

		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India		
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)		
Description of Pack (Container closure system)	White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-00.3
Batch Size	500 sachet	500 sachet	500 sachet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	28-06-2022	28-06-2022	28-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-02-2024.
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify	• We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP.
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	**Sodium Bicarbonate:** TaTa Chemicals Europe Private Limited., Natrium House Winnington Lane, Northwich, Cheshire CW8 4GW Copy of GMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate is not submitted **Omeprazole:** Firm has submitted copy of cGMP certificate of of API manufacturer issued by Drug Control Administration Government of Telangana India valid upto 12-07-2026
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Sodium bicarbonate is used as buffer in applied formulation so drug substance part is N/A for this.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is submitted. • Copy of Certificate of analysis for Omeprazole B# OME-P/22006 Metrochem API (Pvt) Ltd. is submitted.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.	• Copy of Certificate of analysis for Omeprazole working standard submitted.

3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• We have added sodium bicarbonate as a buffer because the stability of omeprazole is pH-dependent. It is rapidly degraded in acidic media but has acceptable stability under alkaline conditions. According to the FDA label of ZEGERID Powder for Oral Suspension (innovator) by Santarus, Inc., a wholly owned subsidiary of Salix Pharmaceuticals, sodium bicarbonate is described under buffer content in subsection 5.5* of the FDA label for ZEGERID Powder for Oral Suspension. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021849s010021636s0161bl.pdf. Additionally, Risek Insta, a competitor product in Pakistan, has also mentioned sodium bicarbonate as a buffer. • However innovator's product uses it as active ingredient
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph	• According to guidelines provided by the Drug Registration Board in its 293rd meeting, the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPMs, and sampling time) are taken from the FDA dissolution method database. The FDA dissolution database specifies a 30-minute sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. We adopted the 30-minute sampling time from the FDA dissolution database for omeprazole/sodium bicarbonate powder for oral suspension. • We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP. pH limits are selected based on experimental data. Additionally, the product also shows maximum dissolution at pH 7.4, which is the recommended pH for the dissolution test in the FDA dissolution method database. All the results of trial batches lie near pH 7.4. • The product monograph for omeprazole/sodium bicarbonate powder for oral suspension is not included in the USP. A validated testing method (MVL-387 & MVL-387 A) is used for testing omeprazole in the omeprazole/sodium bicarbonate sachet. This method is available in the USP for testing omeprazole. A copy of the USP monograph for omeprazole is submitted for reference.

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).	• Detailed raw data sheet for stability testing is submitted • UV absorbance value and spectra for dissolution testing is submitted • Firm has submitted copy of form 6 issued dated 19-04-2022 specifying Sodium Bicarbonate. The invoice is issued by AD (I&E) DRAP. • Documents for procurement of Omeprazole is not submitted

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin**
- **Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation**
- **Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation**
- **Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document**
- **Justification for selecting different limit of pH test (6.5-8.0) in finished product specifications than USP monograph (7.5-8.5)**
- **Documents for the procurement of API with approval from DRAP (in case of import).**

797.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17573 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#307907903)
	The proposed proprietary name / brand name	**Vyber 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……40mg Sodium Bicarbonate……..1680mg (as buffer)
	Pharmaceutical form of applied drug	Powder for oral suspension

	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product

		Risek Insta 40mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India		
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)		
Description of Pack (Container closure system)	White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-00.3
Batch Size	500 sachet	500 sachet	500 sachet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	26-07-2022	26-07-2022	26-07-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • Chromatograms for stability testing at 6th month time point is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-02-2024.
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole	**Sodium Bicarbonate:** TaTa Chemicals Europe Private Limited., Natrium House Winnington Lane, Northwich, Cheshire CW8 4GW

	and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	Copy of GMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate is not submitted **Omeprazole:** Firm has submitted copy of cGMP certificate of of API manufacturer issued by Drug Control Administration Government of Telangana India valid upto 12-07-2026
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify	We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP.
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Sodium bicarbonate is used as buffer in applied formulation so drug substance part is N/A for this.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is submitted. • Copy of Certificate of analysis for Omeprazole B# OME-P/22006 Metrochem API (Pvt) Ltd. is submitted.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.	• Copy of Certificate of analysis for Omeprazole working standard submitted.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• We have added sodium bicarbonate as a buffer because the stability of omeprazole is pH-dependent. It is rapidly degraded in acidic media but has acceptable stability under alkaline conditions. According to the FDA label of ZEGERID Powder for Oral Suspension (innovator) by Santarus, Inc., a wholly owned subsidiary of Salix Pharmaceuticals, sodium bicarbonate is described under buffer content in subsection 5.5* of the FDA label for ZEGERID Powder for Oral Suspension. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021849s010021636s0161bl.pdf. Additionally, Risek Insta, a competitor product in Pakistan, has also mentioned sodium bicarbonate as a buffer. • However innovator's product uses it as active ingredient
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-	• According to guidelines provided by the Drug Registration Board in its 293rd meeting, the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPMs, and sampling time) are taken from the FDA dissolution method database. The FDA dissolution database specifies a 30-minute

	8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph	sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. We adopted the 30-minute sampling time from the FDA dissolution database for omeprazole/sodium bicarbonate powder for oral suspension. • We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP. pH limits are selected based on experimental data. Additionally, the product also shows maximum dissolution at pH 7.4, which is the recommended pH for the dissolution test in the FDA dissolution method database. All the results of trial batches lie near pH 7.4. • The product monograph for omeprazole/sodium bicarbonate powder for oral suspension is not included in the USP. A validated testing method (MVL-387 & MVL-387 A) is used for testing omeprazole in the omeprazole/sodium bicarbonate sachet. This method is available in the USP for testing omeprazole. A copy of the USP monograph for omeprazole is submitted for reference.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • Chromatograms for stability testing at 6th month time point is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).	• Detailed raw data sheet for stability testing is submitted • Chromatograms for stability testing at 6th month time point is submitted • UV absorbance value and spectra for dissolution testing is submitted • Firm has submitted copy of form 6 issued dated 19-04-2022 specifying Sodium Bicarbonate. The invoice is issued by AD (I&E) DRAP. • Documents for procurement of Omeprazole is not submitted

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin**
- **Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation**
- **Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation**
- **Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document**
- **Justification for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5)**

• **Documents for the procurement of API with approval from DRAP (in case of import).**

Case No. 08: Deferred Registration applications of Human drugs on Form 5-F (New Section)

798.	Name, address of Applicant / Marketing Authorization Holder	M/s Siam Pharmaceutical., Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical., Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 17-10-2022 issued based on inspection conducted on 26-01-2022
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-36/2010-Lic (Vol-I) dated 26th May 2022 specifying Sachet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 26043 dated 27-10-2023
	Details of fee submitted	Rs.30,000/- dated 24-10-2023 (Slip#192249834)
	The proposed proprietary name / brand name	**Cellkast 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast Sodium Eq. to Montelukast……4mg
	Pharmaceutical form of applied drug	Granules
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 4mg oral granules USFDA Approved
	For generic drugs (me-too status)	Montika 4mg Sachet by M/s Sami Pharmaceuticals (Reg#50744)
	Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	CDP has been performed against the product Myteka 4mg Sachet by M/s Hiton Pharma in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy and precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang Province, China.		
API Lot No.	11031-220404		
Description of Pack (Container closure system)	White to off white granular powder filled in Megi paper foil further packed in bleach board carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	MK04T004	MK04T005	MK04T006
Batch Size	840 sachet	840 sachet	840 sachet
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	09-2022	09-2022	09-2022
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China issued by China Food and Drug Administration valid till 14-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• The firm has submitted copy of DML#Zhe 20050431 of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China valid till 16-06-2025
3.2.S.4	• Clarification is required as drug product manufacturer has submitted specification of Vortioxetine HBr instead of Montelukast Sodium • The time point and ratio of mobile phase selected for gradient program in assay test of drug substance is different than USP monograph, clarify • Results of specificity test in analytical method verification studies is not submitted. • Submit Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer.	• Firm has submitted specification of Montelukast Sodium • Firm has submitted revised analytical method for assay test as per USP monograph • Firm has submitted results of specificity test in analytical method verification studies • COA of relevant batch of drug substance from drug substance manufacturer is submitted
3.2.P.2	• Pharmaceutical equivalence studies against the innovator/reference product shall be submitted • Details of innovator/comparator product including batch number, manufacturing date, expiry date against which CDP studies is performed shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Myteka 4mg sachet by M/s Hilton Pharma. • Details of comparator product is submitted Btach#144293, Mfg date; 06-2022, Exp date; 06-2024

3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per USP monograph	• Firm has submitted the results of uniformity of dosage units test
3.2.P.6	• Clarification is required since the submitted COA of reference / working standard states that it follows in house specifications while the product monograph is available in USP • You have submitted COA of Montelukast sodium working reference standard while USP monograph recommends the use of Montelukast Dicyclohexylamine as reference standard in analytical method, clarify	• Firm has submitted another COA of working reference standard and it follows USP specifications • The firm submitted that as per claimed composition we can use montelukast sodium as working reference standard because we are concerned about montelukast not sodium and dicyclohexylamine
3.2.P.8	• Stability study data at 6th month time point is not submitted • The batch number of API mentioned in stability summary sheets (11002-220305) is different than that submitted in batch analysis of drug substance (11031-220404) clarify • Documents for the procurement of API with approval from DRAP (in case of import).	• Stability study data at 6th month time point is submitted • Firm has submitted batch analysis of API batch# 11002-220305 • Firm has submitted copy of clearance certificate for import of 10kg Montelukast Sodium USP (Batch#11031-220404) in name of M/s Siam Pharmaceuticals., attested by AD (I&E) DRAP Islamabad dated 23-08-2022. Clearance certificate of different batch No. of API is submitted

Previous Decision (M-335th-DRB): Deferred for submission of following:

- Clarification for using Montelukast sodium working reference standard in analytical method instead of Montelukast Dicyclohexylamine as reference standard as recommended by USP monograph.
- Clearance certificate or commercial invoice attested by AD (I&E) DRAP of relevant batch of API

Firm's Response:

S No	Observations	Firm's response
1	• Clarification for using Montelukast sodium working reference standard in analytical method instead of Montelukast Dicyclohexylamine as reference standard as recommended by USP monograph.	• The firm submitted that we mistakenly attached the COA of Montelukast Sodium as reference standard due to availability of both reference standards COA's, now here is attached the correct COA of Montelukast Dicyclohexylamine as per USP monograph
2	• Clearance certificate or commercial invoice attested by AD (I&E) DRAP of relevant batch of API	• Firm has submitted copy of clearance certificate for import of 10kg Montelukast Sodium USP (Batch#11031-220404) attested by AD (I&E) DRAP Islamabad dated 23-08-2022. Firm has also submitted COA of the relevant batch of API. The firm has submitted revised stability summary sheets in which batch number of relevant batch of API is mentioned

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**

i.	**Fee Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 09: Deferred Registration applications of Human drugs on Form 5-F (New Section)

799.	Name, address of Applicant / Marketing Authorization Holder	M/s Pearl Pharmaceuticals., Plot #204, Street# 01, I-10/3 Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals., Plot #204, Street# 01, I-10/3 Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-02-2023 based on inspection conducted on 03-11-2022.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-18/90-Lic (Vol-III) dated 21st February 2023 for Renewal of Drug Manufacturing License / Regularization / New Sections specifying Ampoule (General)-New section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID; 9NE-PPY-TDQ4 dated 23-02-2024
	Details of fee submitted	PKR 30,000 /- Dated 09-02-2024 (Deposit slip# 19834350466)
	The proposed proprietary name / brand name	**D-Pearl 5mg/ml Ampoule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1ml ampoule contains; Cholecalciferol……5mg (200,000I.U)
	Pharmaceutical form of applied drug	Ampoule
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Reference to Finished product specifications	Innovators Specification
	Proposed Pack size	1x1ml ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VITAMIN D3 GOOD 200,000 IU/1 ml, IM injection solution in ampoule ANSM (France) Approved
	For generic drugs (me-too status)	Indrop-D Injection by M/s Neutro Pharma (Reg#023170)
	Name and address of API manufacturer.	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 06 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Indrop-D Injection by M/s Neutro Pharma.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, linearity, range, accuracy, precision (repeatability, intermediate), robustness, LOD, LOQ.

STABILITY STUDY DATA	
Manufacturer of API	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China.
API Lot No.	221223
Description of Pack (Container closure system)	Clear and colorless solution filled in clear transparent glass ampoule (USP Type I) free from visible foreign particles fitted in plastic Ampoule protector and further packed in Unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	D-T2	D-T3	D-T4
Batch Size	1000 Ampoule	1000 Ampoule	1000 Ampoule
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	28-08-2023	28-08-2023	28-08-2023
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of License (DML#20160429) of M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China. issued by Sichuan Food & Drugs Administration valid upto 18-10-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted letter for borrowing of raw material (12gm) for stability batches from Bio-Lab Pharmaceuticals, along with copy of form 5 and clearance certificate.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Complete Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.S.7	• Submit stability study data of drug substance at real time conditions as per zone IV-A conditions till claimed shelf life
3.2.P.2	• Details of reference product including, manufacturing date and expiry date shall be provided
3.2.P.5	• The analytical method for sterility test is not submitted for the applied product • Numerical value of results shall be reported in the test for standard volume instead of writing complies in batch analysis

3.2.P.8	• Justify the quantity of API required for manufacturing of three batches of 1000 ampoules • Stability study data at 6th month time point for applied product is not submitted • Chromatograms of batch# D-T2 at 3rd month time point of stability testing (both accelerated and real time conditions) is not submitted

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Complete Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted • Complete Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of working reference standard is submitted
3.2.S.7	• Submit stability study data of drug substance at real time conditions as per zone IV-A conditions till claimed shelf life	• Stability study data of drug substance at real time conditions as per zone IV-A conditions till claimed shelf life is not submitted
3.2.P.2	• Details of reference product including, manufacturing date and expiry date shall be provided	• Details of reference product including, manufacturing date and expiry date is submitted Product: Indrop-D Mfg date: 09/22 Exp date: 09/26
3.2.P.5	• The analytical method for sterility test is not submitted for the applied product • Numerical value of results shall be reported in the test for standard volume instead of writing complies in batch analysis	• The analytical method for sterility test is submitted • Numerical value of results is reported in the test for standard volume and submitted revised COA
3.2.P.8	• Justify the quantity of API required for manufacturing of three batches of 1000 ampoules • Stability study data at 6th month time point for applied product is not submitted • Chromatograms of batch# D-T2 at 3rd month time point of stability testing (both accelerated and real time conditions) is not submitted	• The firm submitted that we borrowed Cholecalciferol, totaling 24gm, from the bio lab on two separate occasions. While the first acquisition was documented in the CTD dossier, regrettably, the second one was omitted. We have now included both correspondences for your reference. Loan letter for borrowing of additional raw material (12gm) is submitted • Stability study data at 6th month is submitted. • Chromatograms of Batch# D-T2 at 3rd month time point of stability testing is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Stability study data of drug substance at real time conditions as per zone IV-A conditions till claimed shelf life**

Case No. 10: Deferred Registration applications of Human Drugs on form 5F (New DML):

800.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28775 dated 11-10-2022
	Details of fee submitted	Rs.30,000/- dated 14-07-2022 (Deposit Slip#01492435)
	The proposed proprietary name / brand name	OmeGen 20mg/1680mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Omeprazole……...20mg Sodium bicarbonate……1680mg
	Pharmaceutical form of applied drug	Immediate Release Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator Specefications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist. Telangana India **Sodium Bicarbonate:**

		M/s United Chem., 18-Warlley Moor Lane Leeds West Workshire LS 12 4HX United Kingdom
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Omeprazole:** Firm has submitted stability study data of omeprazole. Stability study is conducted at accelerated conditions; ***25°C ± 2°C / 60% ± 5%RH for 06 months*** and at Real time conditions; ***2-8°C*** ± for 36 months Batches: OM/004/10, OM/005/10, OM/006/10)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the product that is Zegerid 20mg IR Powder for oral suspension by M/s Santarus Inc. by performing quality tests (Identification, Assay, Dissolution, content uniformity). CDP has been performed against the same brand that is Zegerid 20mg IR Powder for oral suspension by M/s Santarus Inc. in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	In method Validation studies only results for accuracy, precision is submitted.
STABILITY STUDY DATA		
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist. Telangana India **Sodium Bicarbonate:** M/s United Chem., 18-Warlley Moor Lane Leeds West Workshire LS 12	

	4HX United Kingdom		
API Lot No.	**Omeprazole:** OME/E-143/21 **Sodium Bicarbonate:** 547908		
Description of Pack (Container closure system)	Aluminum foil Sachet packed in packing box		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	2000 Sachet	2000 Sachet	2000 Sachet
Manufacturing Date	09/2021	09/2021	09/2021
Date of Initiation	10-09-2021	10-09-2021	10-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted GMP certificate No# L.Dis.No:64180/TS/2021 dated 09/08/2021 in name of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist. Telangana India valid upto 08/08/2022. **Sodium Bicarbonate:** M/s United Chem., 18-Warlley Moor Lane Leeds West Workshire LS 12 4HX United Kingdom
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	
1.5.6	• You have applied for innovator specifications while the monograph for the applied product is available in USP. Revise your specification as per USP monograph along with submission of applicable fee	
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient sodium bicarbonate by Drug substance manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient sodium bicarbonate by Drug product manufacturer is required. • Results of specificity test for dug substance omeprazole is not submitted • Provide evidence of Atomic Absorption Spectroscopy used for analysis of calcium, mg, copper in sodium bicarbonate as per results given in batch analysis • The limits of assay test for sodium bicarbonate in USP is 99-100.5 while drug substance manufacturer and drug product manufacture have followed 99-101 in batch analysis	
3.2.S.7	• Submit stability study data of drug substance omeprazole and sodium bicarbonate as per zone IV-A conditions	
3.2.P.5	• Test for pH is not included in specification although recommended by USP monograph • Justification is required since limits of dissolution specification of applied drug product (Q 75 in 30 min) is different than that recommended by innovator product review document (Q 75 in 15min). • Justification is required for not included the limits of sodium bicarbonate in dissolution test in submitted specifications • Submit complete analytical procedure for applied product • Submit method verification studies for applied product	
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP. • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Previous Decision (M-332nd-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's Response:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	• The firm submitted that the name of applicant is Biogen Pharmaceuticals, while mentioning Biogen Lifesciences in section 1.3.1 & 1.3.2 is a drafting error
1.5.6	• You have applied for innovator specifications while the monograph for the applied product is available in USP. Revise your specification as per USP monograph along with submission of applicable fee	• The firm submitted that latest edition of USP does not include the monograph
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	• Firm has GMP certificate of drug substance manufacturer for omeprazole • **Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist. Telangana State India Valid upto 14-08-2023 • Copy of cGMP certificate / DML for Sodium Bicarbonate is not submitted

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient sodium bicarbonate by Drug substance manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient sodium bicarbonate by Drug product manufacturer is required. • Results of specificity test for dug substance omeprazole is not submitted • Provide evidence of Atomic Absorption Spectroscopy used for analysis of calcium, mg, copper in sodium bicarbonate as per results given in batch analysis • The limits of assay test for sodium bicarbonate in USP is 99-100.5 while drug substance manufacturer and drug product manufacture have followed 99-101 in batch analysis	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer is submitted. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug product manufacturer is submitted. • Results of specificity test for dug substance omeprazole is submitted • The firm submitted that the values for elemental metals were taken from manufacturer's COA. • The firm submitted that it was through your good office that we were able to know that there was a variation in acceptable limit of sodium bicarbonate i.e., 99 to 101, definitely there was a drafting error from supplier and eventually from Finished Product manufacturer. However it can be assured from 3.2.S.4.1 & 3.2.S.4.2 & 3.2.S.4.7 Sections that acceptance criteria was 99 to 100.5 as defined by USP.
3.2.S.7	• Submit stability study data of drug substance omeprazole and sodium bicarbonate as per zone IV-A conditions	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
3.2.P.5	• Test for pH is not included in specification although recommended by USP monograph • Justification is required since limits of dissolution specification of applied drug product (Q 75 in 30 min) is different than that recommended by innovator product review document (Q 75 in 15min). • Justification is required for not included the limits of sodium bicarbonate in dissolution test in submitted specifications • Submit complete analytical procedure for applied product • Submit method verification studies for applied product	• The firm submitted that latest edition of USP does not include the monograph • The firm submitted that as identified by your office, clinical Pharmacology & Biopharmaceutics review states dissolution time limit of 15 minutes, we hereby update our SAP with stated dissolution time & CDP studies makes it evident that our product release is 88% in 15 minutes. • No reply submitted • Complete analytical procedure for applied product is submitted • Method verification studies for applied product is submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP. • Submit Record of Digital data logger for temperature and humidity	• Firm has submitted copy of commercial invoice specifying 250gm omeprazole powder. However, invoice is not cleared by AD (I&E) DRAP. Firm has submitted copy

	monitoring of stability chambers (real time and accelerated)	of goods declaration and courier documents for import of omeprazole • Firm has submitted copy of commercial invoice specifying 10Kg Sodium Bicarbonate. However, invoice is not cleared by AD (I&E) DRAP. Firm has submitted copy of goods declaration and courier documents for import of sodium bicarbonate • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin**
  - **ii. Fee Rs. 30,000/- for correction/pre-approval change/ in name of applicant, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 11; Deferred Registration application of Human drugs on Form 5-F on export facilitation

801.	Name, address of Applicant / Marketing Authorization Holder	M/s Macter International Ltd., F-216, SITE, Karachi-Pakistan.
	Name, address of Manufacturing site.	M/s Macter International Ltd., F-216, SITE, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 05-08-2022 based on inspection conducted on 04-08-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-13/95-Lic (Vol-III) dated 10-12-2019 which specifies injectable section (ceph)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 843 dated 10-01-2023
	Details of fee submitted	Rs.30,000/- dated 10-10-2022 (Deposit slip#387617737581)
	The proposed proprietary name / brand name	Avicef 2.5gm Powder for Injection

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime as Ceftazidime pentahydrate……..…2g Avibactam as avibactam sodium ……0.5g
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Ceftazidime belongs to the group of antibiotics called "cephalosporin" Avibactam is "beta-lactamase inhibitor"
	Reference to Finished product specifications	Not submitted
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion MHRA Approved Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion TGA Approved AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved
	For generic drugs (me-too status)	Zavicefta Injection 2g/0.5g Powder for Concentrate for Solution for Infusion by M/s Pfizer Pakistan Ltd (Reg#106848)
	Name and address of API manufacturer.	M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (180601, 180602, 180603)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand that is Avycaz 2.5g Powder for injection by M/s GSK Italy., by performing quality tests (Appearance, identification, average weight, pH, Assay

		and related substances).		
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, accuracy, precision, specificity and robustness.		
STABILITY STUDY DATA				
Manufacturer of API	M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China			
API Lot No.	2105001			
Description of Pack (Container closure system)	25cc Clear glass vial, rubber stopper, flip off seal and leaflet in unit carton (1's)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	21SB-077-001	21SB-078-002	21SB-079-003	
Batch Size	100 Vials	100 Vials	100 Vials	
Manufacturing Date	07-09-2021	07-09-2021	07-09-2021	
Date of Initiation	09-2021	09-2021	09-2021	
No. of Batches	03			
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, China issued by China Food and Drug Administration valid upto 21-02-2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 01-04-2020 for import of 1kg of Avibactam and Ceftazidime sterile (Working standard & Impurities) in name of M/s Macter International Limited. ***However, the invoice is not attested by AD (I&E) DRAP field office.***		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator [XI]:				
Sectio	**Observations**	**Response**		

n		
1.5.6	• Mention the reference specifications of the finished product	• The firm has mentioned Innovator's specifications for applied product
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of DML (License#Nei20160028) in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District, Chifeng, China issued by Drug Administration of Nei Monggol China valid upto 27-12-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing the test for content uniformity and pyridine content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Firm has submitted analytical method validation studies including linearity, accuracy, precision, specificity and robustness performed by the Drug Product manufacturer for drug substance. • Test for content uniformity has been performed by drug product manufacturer and revised reports submitted. *However, test for pyridine content is not submitted.*
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	• The firm submitted that sterile water for injection will be provided with applied drug product that is already registered with M/s Macter International
3.2.P.2	• Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, pyridine content, uniformity of dosage unit, particulate matter, water content, bacterial endotoxins and sterility)	• Firm has submitted the justification on Pharmaceutical Equivalence included complete testing (Appearance, Identification, Avg. weight, pH, Assay, Related Substance, Any unspecified impurity, Total Impurity) of the drug product Avicef 2.5 g powder for injection and the innovator product recommended by the following guidelines, "Pharmaceutical equivalence – Drug products are considered pharmaceutical equivalents if they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product [1, 2]".Report of pharmaceutical equivalence is submitted. • Also the equivalence relationships between brand name and generic drugs are the following parameters; (API, Dosage form, Dose, Route of Administration, Labeling. • The test parameters stated in query already performed in our in-house testing

		for finished product.
3.2.P.3	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Macter International Ltd. • Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product	• No justification is submitted for batch size of trial batches against the number of units required for complete testing of drug product during stability study till claimed shelf life • The firm submitted that batch size was determined according to the standard mixture, which is 315.0g for 100vials. The firm further stated that batch was filled according to the potency of API, which was tested by M/s Macter International. • Firm has submitted that content sodium carbonate in premixed drug substance has been corrected and mentioned Certificate of Analysis for drug substance and stated that COA is submitted in dossier.
3.2.P.5	• Justification is required for not including the test for reconstitution time, pyridine content, uniformity of dosage unit and water content in finished product specification by drug product manufacturer as recommended by innovator product review document • Justification is required for not performing the test for reconstitutions time, uniformity of dosage units, pyridine content and water content in batch analysis by drug product manufacturer as recommended by innovator product review document	• Firm submitted that reconstitution time, uniformity of dosage unit and water content tests were already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test performed and mentioned in revised report of the drug substance of Avicef 2.5 g powder for injection. *However results for uniformity of dosage unit is not submitted*
3.2.P.7	• Description of the primary container closure systems including the type of glass shall be submitted	• Clear glass vial 25cc
3.2.P.8	• Justification is required for not performing the test for reconstitutions time, uniformity of dosage units, pyridine content and water content in stability study by drug product manufacturer as recommended by innovator product review document • Submit document for procurement of API with approval from DRAP	• Firm submitted that test for reconstitution time, uniformity of dosage unit and water content were already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test *will be perform in ongoing stability study of the drug substance Avicef 2.5 g powder for injection. However, no revised reports are submitted* • Firm has submitted copy of invoice dated 17-06-2021 for import of 1kg of Avibactam and Ceftazidime sterile (& Impurities) in name of M/s Macter International Limited attested by AD (I&E) DRAP Karachi dated 22-06-2021

Previous Decision (M-330th-DRB): Deferred for submission of following:

- Justification for not performing the test for pyridine content in batch analysis of drug substance by drug product manufacturer
- Justification as pharmaceutical equivalence study report does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product

review document (description on reconstitution, reconstitution time, pyridine content, uniformity of dosage unit, particulate matter, water content, bacterial endotoxins and sterility)

- Justification for the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life
- Justification for not including the test for reconstitution time, pyridine content, uniformity of dosage unit and water content in finished product specification by drug product manufacturer
- Results for uniformity of dosage unit in batch analysis of drug product
- Reports for reconstitution time, uniformity of dosage unit, water content in stability study
- Results for pyridine content in ongoing stability study

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Justification for not performing the test for pyridine content in batch analysis of drug substance by drug product manufacturer	• The firm submitted that the test for content uniformity and pyridine content in the batch analysis of the drug substance of Avicef 2.5 g powder for injection has been performed, and the revised reports are submitted.
2	• Justification as pharmaceutical equivalence study report does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, pyridine content, uniformity of dosage unit, particulate matter, water content, bacterial endotoxins and sterility)	• The firm submitted that pharmaceutical equivalence study included the complete testing (Appearance, Identification, Avg. weight, pH, Assay, Related Substance, Any unspecified impurity, Total Impurity) of the drug product Avicef 2.5 g powder for injection and the innovator product recommended by the following guidelines, • "Pharmaceutical equivalence - Drug products are considered pharmaceutical equivalents if they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product [1, 2]". Report of pharmaceutical equivalence is submitted. • Also, the equivalence relationships between brand name and generic drugs are on the following parameters [3], [API, Dosage form, Dose, Route of administration, Labelling]. • The test parameters stated in query already performed in our in-house testing for finish product and CoA with method is submitted herewith.
3	• Justification for the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	• The firm submitted that the batch size of trial batches against the number of unit required for complete testing of drug product during stability has been mentioned "SOP for batch size selection criteria for injectable dosage form, DOC no. SUP/RND/PP/002" for drug substance of Avicef 2.5 g powder for injection". • As per the DRAP Guidance Document [I], the firm selected the scientifically justified batch size through thorough testing, as also outlined in Document No. SUP/RND/PP/002. • The firm submitted that a total of 85 vials are required for complete testing throughout proposed life while 10-15 vials are used in IPC

		for weight variation and vials for weight adjustments
4	• Justification for not including the test for reconstitution time, pyridine content, uniformity of dosage unit and water content in finished product specification by drug product manufacturer	• The firm submitted that the test for reconstitution time, uniformity of dosage unit and water content already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test performed and mentioned in revised report of the drug substance of Avicef 2.5 g powder for injection
5	• Results for uniformity of dosage unit in batch analysis of drug product	• The firm submitted that the Uniformity of dosage unit was assessed during the filling process, and the corresponding In-Process Control (IPC) sheets are attached. Additionally, the uniformity of dosage units was evaluated by measuring the weight variations in all three batches, and the results have already been provided".
6	• Reports for reconstitution time, uniformity of dosage unit, water content in stability study	• The firm submitted that the test for reconstitution time, uniformity of dosage unit and water content already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test has been performed in ongoing stability study of Avicef 2.5 g powder for injection".
7	• Results for pyridine content in ongoing stability study	• Results for pyridine content in ongoing stability study is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 12: Deferred routine registration applications of Human Drugs on Form 5F

802.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma (Pvt.) Ltd., 27-Sundar Industrial Estate, Sundar Raiwand RD Lahore
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 which specifies Liquid Injection (Ampoule, Vial, Infusion) (General) section

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3625 dated 08-02-2022
	Details of fee submitted	PKR 75,000/-: dated: 04-01-2022 (Deposit sip#98940276970)
	The proposed proprietary name / brand name	**Irfen Injection 100mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ferric hydroxide polymaltose complex equivalent to Iron(III)……100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Use to treat Iron deficiency
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5's x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ferrosig Injection 100mg/2ml by M/s Sigma Company Limited., TGA Approved
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 36 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 002 FP 01, FPJ 003 FP 01, FPJ 004 FP 01)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification

		of specification, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Hemafer 100mg/2ml Injection by M/s UNI-PHARMAKLEON LAORATORIES S.A by performing quality tests (Identification, pH, Assay)
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, Accuracy, Precision-Repeatability, Intermediate Precision, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy		
API Lot No.	FPJ014FV20		
Description of Pack (Container closure system)	Amber glass Type I ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C /65%± 5%RH Accelerated: 40˚C ± 2˚C / 75%± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(A)-098-01	21SB(A)-099-02	21SB(A)-100-03
Batch Size	500ampoules	500ampoules	500ampoules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-07-2021	15-07-2021	15-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy issued by Italian Medicines Agency valid upto three years from the date of inspection (date of inspection 28/06/2019)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for three months is submitted

THERAPEUTIC INDICATIONS

FERROSIG is indicated for the treatment of iron deficiency anaemia in the following circumstances:

- When oral therapy is contraindicated.
- When enteric absorption of iron is defective.
- When patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of panel inspection report of the applicant for renewal of DML dated 08-02-2021 & 27-10-2021 wherein panel recommends the grant of renewal of DML by way of formulation to M/s Daneen Pharma (Pvt.) Ltd., 27-Sundar Industrial Estate, Sundar Raiwand RD Lahore • *GMP inspection report/ GMP certificate of the manufacturing unit is not submitted*
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference	• Parenteral iron preparations. Anti-anaemic
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm submitted clarification from AIFA Italy stating that due to restrictions caused by covid-19, the period of validity of the GMP certificate is automatically extended until the end of 2023. Onsite inspections will resume as soon as there is a consensus that the period of public health crisis has passed
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Not submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	According to Biofer MOA no working standard are required for release analysis of the API Ferric Hydroxide Polymaltose Complex so, we cannot provide any CoA.
3.2.S.7	• Results of Assay test for iron is not submitted in stability study of drug substance, clarify	Firm submitted revised stability study data of drug substance wherein Assay test for iron has been performed. Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 60 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 001 FV 17, FPJ 005 FV 16, FPJ 006 FP 15)
3.2.P.1	• Justification is required for not using hydrochloric acid or sodium hydroxide for pH adjustment in formulation	• In development of Genfer Injection 100mg/2ml, the active substance (Ferric Hydroxide Polymaltose Complex Inj.Grade) is dissolved in water for injection and mix until homogenization of solution will be formed. Then Check the pH of the solution. pH limit = 5.2 – 6.50.

		• The pH of the solution observed in the range as described above therefore no need to the addition of HCl or NaOH for pH adjustment in the formulation. • The product kept on stability and no changes observed in pH of the formulation and any other physical and chemical parameters. • Stability studies also demonstrated that the formulation is stable without the addition of pH adjusting agents.
3.2.P.2	• Submit details of country of origin of reference product against which pharmaceutical equivalence studies have been performed. • Justification is required for not performing test for bacterial endotoxin and particulate matter in pharmaceutical equivalence as submitted in finished product specifications	• The firm submitted details of country of origin: UNI-PHARMA KLEON TSETIS Pharmaceutical Laboratory S.A 14Km National Road 1, GR-145 64K, Kifissia GREECE. • The firm submitted that we have also conducted pharmaceutical equivalence against Ferrosig 100mg/2ml injection by M/s Sigma Company Limited Rowville, VIC, 3176 Australia by performing quality test (Appearance, Identification, pH, Assay, BET, Particulate matter) • The firm has submitted revised pharmaceutical equivalence report wherein results of test for bacterial endotoxin and particulate matter has been submitted
3.2.P.5.2	• You have applied for innovator specifications in module 1 section 1.5.6 while in-house specification in this section, justify?	The firm submitted that this is typographic error and submitted revise specification stating innovator specifications
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	The firm submitted that we have conducted assay of Iron by complexometric titration, in this method working standard is not required.
3.2.P.8	• You have written liraglutide on initial page of summary sheet while applied product is ferric hydroxide polymaltose complex, clarify? • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 6th months is required • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit 6th month stability data of applied product	• The firm submitted that this is typographic error and submitted corrected summary reports. • Audit trial is not applicable as product testing is carried out via titration method • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted • Firm has submitted copy of invoice for import of 01Kg of Ferric Hydroxide Polymaltose Complex (Batch No# FPJ014FV20) in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021. • Firm has also submitted copy of form 6 for import of 01Kg of Ferric Hydroxide Polymaltose Complex in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021. • 6th month stability data of applied product is submitted

Previous Decision (M-329-DRB): Deferred for submission of following:

- Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer.
- GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years
- Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Firm's Response:

Section	Observations	Response
1	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted
2	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years	**M/s Genix Pharma** Firm has submitted copy of cGMP certificate of M/s Genix Pharma dated 13-06-2023 based on inspection conducted on 06-06-2023 **M/s Daneen Pharma** Firm has submitted copy of cGMP certificate of M/s Daneen Pharma dated 02-02-2022 based on inspection conducted on 27-10-2021
3	• Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	• Firm has submitted fee Rs. 7,500/- for correction/pre-approval changes in specifications vide deposit slip#38798134.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

803.	Name, address of Applicant / Marketing Authorization Holder	M/s Faas Pharmaceuticals (Pvt.) Ltd., Plot# F-748 L, S.I.T.E Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Safe Pharmaceuticals (Pvt.) Ltd., Plot# C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	**M/s Safe Pharmaceuticals:** Firm has submitted copy of cGMP certificate date 13-08-2020 based on inspection conducted on 13-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Dry Powder Injectable (Cephalosporin) of M/s Safe Pharmaceuticals
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10624 dated 26-04-2022
	Details of fee submitted	Rs.50,000/- dated 28-04-2021 (Deposit slip#9115296832) Rs.25,000/- dated 24-12-2021 (Deposit slip#1184490481)
	The proposed proprietary name / brand name	**Faascef 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Ceftriaxone sodium 250mg
	Pharmaceutical form of applied drug	Dry powder Injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1x250mg
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg Powder for solution for injection MHRA Approved
	For generic drugs (me-too status)	Arizon Injection 250mg IV by M/s Aries Pharmaceuticals (Reg.No# 100241)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batches: 11302001, 11302002, 11302003)
	Module-III (Drug Product):	Firm has submitted data of drug product including

		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Cefxone Injection 250mg by M/s Bosch Pharmaceutical Company by performing quality tests (Description, identification, water, pH, sterility test, BET, particulate matter, assay).
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Specificity, Linearity and range, system suitability

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China		
API Lot No.	Q011801001, Q011712039, ***Q011802027***		
Description of Pack (Container closure system)	White or almost white crystalline powder filled in clear glass vial of 10ml sealed with grey rubber stopper & AI/PI (dark blue) flap (5ml WFI is also supplied in white PVC tray) along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DI-659 ***(API Q011712039)***	DI-710 (API Q011801001)	DI-740 (API Q011802027)
Batch Size	33333 vials	33333 vials	33333 vials
Manufacturing Date	02-2018	05-2018	08-2018
Date of Initiation	23-02-2018	23-05-2018	15-08-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China issued by Shanxi Provincial Food and Drug Administration China valid upto 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No#W180507 dated 07-05-2018 for import of 700kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011802027, Q011802044, Q011802045) in

		name of M/s Safe Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 28-06-2018. Firm has submitted copy of another commercial invoice No#W180347 dated 28-03-2018 for import of 500kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011712037, ***Q011712039***, Q011712100, ***Q011801001***) in name of M/s Safe Pharmaceuticals. *However, the invoice is not attested by AD (I&E) DRAP office.*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Clarification is required as the fee Rs. 50,000/- is submitted on 28-04-2021while R&I date of submitted application is 26-04-2022. (almost 1 year before R&I date)	• The primary reason for the delayed submission of required documents was the discovery of a deficiency in the dossier during pre-screening process. Additionaly we acknowledge that the stability data provided in the initial submission was incomplete.
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years	Firm has submitted cGMP certificate of applicant M/s Faas Pharmaceuticals: Details are: Firm has submitted copy of cGMP certificate date 08-05-2018 based on inspection conducted on 04-05-2018. However, the cGMP in not valid.
1.4.3	• The firm has submitted application to Deputy Director General (R-II) DRAP Islamabad for change of contract manufacturer from M/s PharmEvo (Pvt) Ltd to M/s Safe Pharmaceuticals (Pvt) Ltd. Clarification is required whether it is application for new registration or change of contract manufacturer	• The firm submitted that the application for this product from M/s Safe Pharmaceuticals is for new registration on contract manufacturing with M/s Faas Pharmaceuticals.
1.5.2	• Submit your label claim as per reference formulation along with submission of applicable fee	• Not submitted
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Not submitted
3.2.S.4	• Justification shall be submitted for not including the test for constituted solution, particulate matter, bacterial endotoxin, sterility in drug substance specification by drug product manufacturer as recommended by drug substance manufacturer	• Firm has submitted revised drug substance specificatins in which test for particulate matter, bacterial endotoxin, sterility are included

	• Justification shall be submitted for selecting different limits of assay test by drug product manufacturer (≥79%) than drug substance manufacturer (NLT84%)	• The firm submitted that assay limit as specified by drug substance manufacturer NLT 84% is according to Chinese Pharmacopiea 2010 as provided by Sinopharm. While QC department of M/s Safe Pharmaceuticals has followed USP 36 which specifies assay limit NLT 79.5%
3.2.P.1	• You have submitted the use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection, clarify	• Firm submitted that sterile WFI is complemenatry for parenteral products. We provide 5ml WFI ampoule with our product Faascef 250mg injection although the reconstitution volume required is 2.5ml to prepae the exact dose in accordance with innovator's product.
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by USP monograph (uniformity of dosage unit and test for water determination)	• Firm has submitted pharmaceutical equivalence of their product against the product Rocephin 250mg Injection by M/s Roche Laboratories Inc. by performing quality tests (Description, identification, water, pH, uniformity of dosage unit, assay and reconstituted solution). However details of innovator product i.e batch No#, manufacturing date and expiry date is not provided. Furthermore, test for sterility test, BET, particulate matter are also not performed in pharmaceutical equivalence study.
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units as per USP monograph • Justification shall be submitted using different length column in chromatographic method for assay test (15cm) than USP (25cm). • Results for accuracy and precision studies in analytical method verification for applied product shall be submitted	• Firm has submitted revised finished product specifications in which test for uniformity of dosage units are included. • Firm has submitted revised analytical method for assay test with column length 25cm as per USP • Results for accuracy and precision studies in analytical method verification for applied product is submitted
3.2.P.8	• Submit documents of relevant batches for procurement of API with approval from DRAP • As per submitted COA of API (***Q011712039,*** Q011801001) by drug product manufacturer the analysis date of API is subsequent to the manufacturing date of trial batches clarify • As per submitted stability summary sheet and commercial invoice the manufacturing date of trial batch DI-659 is prior to the import of API, clarify • Clarification shall be submitted as the brand name mentioned in BMR is Safetrazone 250mg injection while analytical record (raw data sheet, stability summary sheet, chromatograms) in batch	• Firm has submitted copy of another commercial invoice No#WQD201704114 dated 26-12-2017 for import of 300kg of Ceftriaxone Sodium Sterile USP (Batch No# *Q011801001, Q011802027, Q011712039*) in name of M/s Safe Pharmaceuticals. *However, the invoice is not attested by AD (I&E) DRAP office.* • No clarification is submitted • No clarification is submitted. However, another invoice is submitted and the invoice is not attested by AD (I&E) DRAP office. • No clarification is submitted. However, the firm has submitted new BMR with applied brand name of drug product i.e.

	analysis and stability study for Faascef injection 250mg is provided • Clarification shall be submitted as the submitted chromatograms does not show the batch number, sample number, standard or sample solution, time point or storage conditions of stability study and wavelength	Faascef 250mg injection and same batch number. • No clarification is submitted. However, the firm has submitted new chromatograms that contains the batch number, sample number, standard or sample solution, time point or storage conditions of stability study

Previous Decision (M-331st-DRB): Deferred for submission of following:

- Differential fee Rs. 25000/- for contract manufacturing application
- Submit your label claim as per reference formulation along with submission of applicable fee
- Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Clarification for use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection
- Complete testing of the applied drug product and the reference product in pharmaceutical equivalence including the tests recommended by USP monograph
- Documents of relevant batches for procurement of API with approval from DRAP
- Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches
- Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)
- Clarification for submission of new BMR with change of brand name

Response of firm:

S No.	Deferment Reason	Firm's Response
1	• Differential fee Rs. 25000/- for contract manufacturing application	• Firm has submitted differential fee Rs. 25000/- on deposit slip#240618745 for contract manufacturing
2	• Submit your label claim as per reference formulation along with submission of applicable fee	• The firm has revised the label claim as per reference formulation. The revise label claim is as under: Each vial of dry substance contains: Ceftriaxone sodium equivalent to ceftriaxone……250mg
3	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Not submitted
4	• Clarification for use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection	• I/we hereby justifies that the required volume to reconstitute Faascef (Ceftriaxone sodium) 250mg injection vial is 2.5ml. We provided 5ml water for injection instead of 3ml water for injection because we have not registered WFI with 3ml and it fulfils the requirement of reconstitution.
5	• Complete testing of the applied drug product and the reference product in pharmaceutical equivalence including the tests recommended by USP monograph	• Firm has submitted pharmaceutical equivalence of their product against the product Cefxone Injection 250mg by M/s Bosch Pharmaceutical
6	• Documents of relevant batches for procurement of API with approval from DRAP	• Firm has submitted copy of commercial invoice No#W180347 dated 28-03-2018 for import of 500kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011712037,

		Q011712039, Q011712100, ***Q011801001***) in name of M/s Safe Pharmaceuticals. attested by AD (I&E) DRAP Karachi dated 09-04-2018.
7	• Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches	• No clarification is submitted
8	• Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)	• No clarification is submitted
9	• Clarification for submission of new BMR with change of brand name	• No clarification is submitted

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches**
- **Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)**
- **Clarification for submission of new BMR with change of brand name**

804.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6131 dated 07-03-2022
	Details of fee submitted	Rs.50,000/- dated 22-02-2021
	The proposed proprietary name / brand name	**K-Met 30mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Ketorolac Tromethamine…….30mg
	Pharmaceutical form of applied drug	IV / IM Injection
	Pharmacotherapeutic Group of (API)	NSAIDs

	Reference to Finished product specifications	USP
	Proposed Pack size	1mlx5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Toradol 30mg/ml Solution for Injection (1ml ampoule) MHRA Approved
	For generic drugs (me-too status)	Toradol Injection 30mg/ml by M/s Martin Dow Marker Limited (Reg# 108584)
	Name and address of API manufacturer.	M/s Saurav Chemicals Limited., 370, Industrial Area, Phase-II Panchkula, Haryana, 134109-India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batches; KTM06180001, KTM06180002, KTM06180003)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Tecak Injection 1ml by M/s Sami Pharmaceuticals by

		performing quality tests (Description, identification, pH, B.E.T., Sterility, assay).		
	Analytical method validation/verification of product	Firm has submitted method verification studies including precision (repeatability, intermediate), linearity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Saurav Chemicals Limited., 370, Industrial Area, Phase-II Panchkula, Haryana, 134109 - India		
API Lot No.		KTM06180003		
Description of Pack (Container closure system)		A clear colorless to light straw color solution, filled in a clear glass printed ampoule of USP type I/II, thermally sealed, placed in plastic tray as 1x5 ampoules and packed in unit carton		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		001	002	003
Batch Size		5000 ampoule	5000 ampoule	5000 ampoule
Manufacturing Date		03-2020	03-2020	03-2020
Date of Initiation		10-03-2020	12-03-2020	16-03-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Saurav Chemicals Limited (Unit-III)., Village Bhagwanpura, Derabassi-Barwala Road, Tehsil Dera Bassi, District Mohali of Punjab state India issued by Directorate of Health and Family Welfare, Punjab, Pariwar Kalyan Bhawan, Sector 34-A, Chandigarh India valid upto two years from the date of issue of this certificate (date of issue of this certificate; 27-08-2010)		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No#SCL/2020-21/056 dated 04-06-2020 for import of 5kg of Ketorolac Tromethamine USP (Batch No#KTM200004) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 01-07-2020. Firm has also submitted copy of commercial invoice No#SCL/NPL/17-18/207 dated 31-01-2018 for import of 5kg of Ketorolac Tromethamine USP (Batch No#KTM170011) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 20-08-2018.		

4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 07th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for not performing the test for loss on drying in batch analysis of drug substance as per BP monograph
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Justification shall be submitted for not performing the test for particulate matter in pharmaceutical equivalence as per USP monograph • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product
3.2.P.3	• Clarification is required as you have mentioned the use of 1.13% overage in master formulation • Justify the performance of terminal sterilization against the reference product literature (autoclave ampoules at 121ºC, 15lb for 20 minutes)
3.2.P.5	• Justification is required for using USP specification for drug product while drug substance is analyzed as per BP monograph by drug substance manufacturer and drug product manufacturer • Justification shall be submitted for not including the test for particulate matter in finished product specifications as per USP monograph

	• Results of analytical method verification studies including accuracy and specificity shall be submitted
3.2.P.7	• Clarification is required regarding the use of clear glass printed ampoule instead of light-resistant containers for finished drug product as per USP
3.2.P.8	• Clarification is required as API from which batch, was used in product development and stability studies as firm has submitted copies of two commercial invoices • The batch No. of API in batch analysis of drug substance is different from that submitted in commercial invoice, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 07th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The firm submitted that fee is submitted on 25-02-2021 while R&I date of submitted application is 07th March 2022. The firm submitted that we initially submitted our application on 10-03-2021, but some deficiencies were found in pre submission screening of CTD. • We re-submitted the file on 07-03-2022 along with deficient documents, that's why there is difference between fee submission date and R&I date of application. • The firm has submitted differential fee Rs. 25000/- on deposit slip o#64480938 dated 30-10-2023 for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F it is mistakenly written while applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying

		Liquid Injection Ampoule / Vial (General Section), LVP section (Blow, Fill, Seal) and SVP section (Blow, Fill, Seal)
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate	• The firm has submitted copy of cGMP certificate of M/s Saurav Chemicals Limited., Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India issued by Food and Drug Administration, Punjab, Ajit Singh Nagar India valid upto two years from the date of issue of this certificate (date of issue of this certificate; 14-06-2019) • No clarification is submitted for difference in address of API manufacturer mentioned in section 1.6.5 and GMP certificate
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for not performing the test for loss on drying in batch analysis of drug substance as per BP monograph	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • The firm has submitted revised batch analysis report of drug substance in which test for loss on drying has been performed
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.2	• Justification shall be submitted for not performing the test for particulate matter in pharmaceutical equivalence as per USP monograph • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	• Firm has submitted revised pharmaceutical equivalence report in which test for particulate matter has been performed. • No justification is submitted
3.2.P.3	• Clarification is required as you have mentioned the use of 1.13% overage in master formulation • Justify the performance of terminal sterilization against the reference product literature (autoclave ampoules at 121ºC, 15lb for 20 minutes)	• The firm has submitted revised master formulation containing no overage. • No justification is submitted

3.2.P.5	• Justification is required for using USP specification for drug product while drug substance is analyzed as per BP monograph by drug substance manufacturer and drug product manufacturer • Justification shall be submitted for not including the test for particulate matter in finished product specifications as per USP monograph • Results of analytical method verification studies including accuracy and specificity shall be submitted	• No justification is submitted. However, the firm has submitted COA of drug substance manufacturer and drug product manufacturer in which testing has been performed as per USP monograph. • Firm has submitted revised finished product specifications in which test for particulate matter has been included • Firm has submitted results of analytical method verification studies including accuracy and specificity.
3.2.P.7	• Clarification is required regarding the use of clear glass printed ampoule instead of light-resistant containers for finished drug product as per USP	• The firm has submitted details of packing material including amber glass ampoule
3.2.P.8	• Clarification is required as API from which batch, was used in product development and stability studies as firm has submitted copies of two commercial invoices • The batch No. of API in batch analysis of drug substance is different from that submitted in commercial invoice, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• No clarification is submitted. • Firm has again submitted copy of commercial invoice No#SCL/2020-21/056 dated 04-06-2020 for import of 5kg of Ketorolac Tromethamine USP (Batch No#KTM200004) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 01-07-2020. The firm has also submitted COA of same batch from drug substance manufacturer • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**
- **Justification for using USP specification for drug product while drug substance is analyzed as per BP monograph by drug substance manufacturer and drug product manufacturer**
- **Clarification as API from which batch, was used in product development and stability studies as firm has submitted copies of two commercial invoices**

805.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.

	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6375 dated 08-03-2022
	Details of fee submitted	Rs.50,000/- dated 27-11-2020 & Rs.25,000/- dated 04-02-2022
	The proposed proprietary name / brand name	**ISC-100 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule of 5ml Contains: Iron Sucrose Complex ……..…100mg
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Anti-anemic
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	5mlx5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule TGA approved
	For generic drugs (me-too status)	Venofer IV Injection by M/s OBS Pakistan Karachi. (Reg. No#085031)
	Name and address of API manufacturer.	M/s SNJ Labs Pvt. Ltd., Plot No. 7, Survey No. 137/2 Om Industrial, Padavala, Tal. Kotdasangani, Dist. Rajkot, Gujarat-India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated

		stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 09 months. (Batches; IS15001, IS15002, IS15003)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Venofer Injection by M/s Vifor Pharma by performing quality tests (Description, identification, pH, sterility, Endotoxin test and assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including precision (repeatability, intermediate), linearity, accuracy and ruggedness.

STABILITY STUDY DATA			
Manufacturer of API	M/s SNJ Labs Pvt. Ltd., Plot No. 7, Survey No. 137/2 Om Industrial, Padavala, Tal. Kotdasangani, Dist. Rajkot, Gujarat-India		
API Lot No.	ISC 190119P5		
Description of Pack (Container closure system)	Amber glass ampoule of 5ml having symmetrical shape, smooth surface, free from cracks and air bubble and practically free from foreign matters		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	09-12-2019	20-12-2019	23-12-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s SNJ Labs Pvt. Ltd., Plot No. 5 to 16, Survey No. 137 at & Post; Padavala, Ta. Kotda Sangani, Dist. Rajkot, India issued by

		Food & Drugs Control Administration Gujarat State India valid upto 21-01-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP/005 (20-21) dated 06-07-2020 for import of 100kg of Iron Sucrose (Batch# P21S20011) in name of M/s M/s Neutro Pharma., attested by AD (I&E) DRAP Lahore dated 10-07-2020. *(mfg date of API; March 2020)*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee Rs. 50,000/- is submitted on 27-11-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year and 03 months before R&I date)
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.5.3	• Revise the label claim as per reference formulation considering the complete salt form along submission of applicable fee
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer is slightly different than that given in GMP
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Clarification is required for submitting batch analysis of drug substance from M/s Pure Chem Pharma Limited and details of drug substance manufacturer in section 1.6.5 & 3.2.S.3 of M/s SNJ Labs Pvt. Ltd., • Justification shall be provided for incomplete analyses of the drug substance by Drug Product manufacturer (specific gravity, osmolarity, turbidity, limit test for Fe (II), chloride content, alkalinity)
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life

3.2.P.1	• Details provided in description and composition of drug product is *each capsule contains; cefalexin as monohydrate…..500mg* while applied product is iron sucrose infusion, clarify?
3.2.P.2	• Justification shall be submitted for not performing the test for chloride content, turbidity, alkalinity, osmolality and osmolarity, specific gravity and particulate matter in pharmaceutical equivalence as per USP monograph
3.2.P.3	• Calculation for dispensed quantity of API in master formulation shall be submitted
3.2.P.5	• Evidence of availability of atomic absorption spectrophotometer as required by the USP monograph of applied formulation. • Justification is required for not including the test for assay of sucrose, content of chloride, alkalinity and absence of low-molecular weight iron [FE(II) AND FE(III)] complexes in finished product specifications • Submit complete analytical procedure for assay of sucrose and iron in analytical method • Justification is required for not performing the test for assay of sucrose, content of chloride, alkalinity, absence of low-molecular weight iron [FE(II) and FE(III)] complexes, particulate matter, osmolarity, turbidity and specific gravity in batch analysis of finished product as per USP monograph • Justification is required as in batch analysis the assay results states that 95-105 % of the stated amount (iron sucrose complex eq. to iron) and results accordingly while no limits and results for sucrose
3.2.P.8	• Justification is required as in stability studies the assay results states that 95-105 % of the stated amount (iron sucrose complex) and results accordingly while no limits and results for sucrose • The batch No. of API (ISC 190119P5) and manufacturer in batch analysis of drug substance is different from that submitted in commercial invoice, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted commercial invoice March 2020 which is subsequent to the manufacturing date (12-2019) of trial batches (as per submitted batch analysis report and stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee Rs. 50,000/- is submitted on 27-11-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year and 03 months before R&I date)	• The firm submitted that fee is submitted on 27-11-2020 while R&I date of submitted application is 08th March 2022. The firm submitted that we initially submitted our application on 29-12-2020, but some deficiencies were found in pre submission screening of CTD. • We re-submitted the file on 08-03-2022 along with deficient documents, that's why there is difference between fee submission date and R&I date of application.
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore

1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F it is mistakenly written while applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section), LVP section (Blow, Fill, Seal) and SVP section (Blow, Fill, Seal)
1.5.3	• Revise the label claim as per reference formulation considering the complete salt form along submission of applicable fee	• No reply submitted
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer is slightly different than that given in GMP	• The firm has submitted copy of cGMP certificate of M/s Pure Chem Pvt. Ltd., plot No. 4717, Near Fikom Chowkadi, GIDC, Ankleshwar-393002, Dist. Bharuch India issued by Food and Drug Control Administration, Gujarat state India valid upto 19-10-2024. The copy of cGMP certificate from a different manufacturer is submitted than that given in form 5F.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Clarification is required for submitting batch analysis of drug substance from M/s Pure Chem Pvt Limited and details of drug substance manufacturer in section 1.6.5 & 3.2.S.3 of M/s SNJ Labs Pvt. Ltd., • Justification shall be provided for incomplete analyses of the drug substance by Drug Product manufacturer (specific gravity, osmolarity, turbidity, limit test for Fe (II), chloride content, alkalinity)	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • No clarification is submitted. However firm has again submitted batch analysis of drug substance from M/s Pure Chem Pvt Limited and M/s Neutro Pharma • Firm has submitted revised batch analysis report of drug substance from drug product manufacturer in which test for specific gravity, osmolarity, turbidity, limit test for Fe (II), chloride content, alkalinity has been performed
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
3.2.P.1	• Details provided in description and composition of drug product is *each capsule contains; cefalexin as monohydrate…..500mg* while applied product is iron sucrose infusion, clarify?	• Firm has submitted details of applied product iron sucrose complex injection in description and composition of drug product
3.2.P.2	• Justification shall be submitted for not performing the test for chloride content, turbidity, alkalinity, osmolality and osmolarity, specific gravity and particulate matter in pharmaceutical equivalence as per USP monograph	• Firm has submitted revised pharmaceutical equivalence report in which test for chloride content, turbidity, alkalinity, osmolality and osmolarity, specific gravity and particulate matter has been performed
3.2.P.3	• Calculation for dispensed quantity of API in master formulation shall be submitted	• Calculation for dispensed quantity of API in master formulation is not submitted
3.2.P.5	• Evidence of availability of atomic absorption spectrophotometer as required by the USP monograph of applied formulation. • Justification is required for not including the test for assay of sucrose, content of chloride, alkalinity and absence of low-molecular weight iron [FE(II) AND FE(III)] complexes in finished product specifications	• Evidence of availability of atomic absorption spectrophotometer is not submitted • Firm has submitted revised finished product specifications in which the test for assay of sucrose, content of chloride, alkalinity and absence of low-molecular weight iron [FE(II) AND FE(III)] complexes is included. • Analytical procedure for assay of sucrose and iron in analytical method is submitted

	• Submit complete analytical procedure for assay of sucrose and iron in analytical method • Justification is required for not performing the test for assay of sucrose, content of chloride, alkalinity, absence of low-molecular weight iron [FE(II) and FE(III)] complexes, particulate matter, osmolarity, turbidity and specific gravity in batch analysis of finished product as per USP monograph • Justification is required as in batch analysis the assay results states that 95-105 % of the stated amount (iron sucrose complex eq. to iron) and results accordingly while no limits and results for sucrose	• Firm has submitted revised batch analysis report in which the test for assay of sucrose, content of chloride, alkalinity and absence of low-molecular weight iron [FE(II) AND FE(III)] complexes, particulate matter, osmolarity, turbidity and specific gravity is performed. • Revised batch analysis report submitted in which test and limits for sucrose have been included and performed
3.2.P.8	• Justification is required as in stability studies the assay results states that 95-105 % of the stated amount (iron sucrose complex) and results accordingly while no limits and results for sucrose • The batch No. of API (ISC 190119P5) and manufacturer in batch analysis of drug substance is different from that submitted in commercial invoice, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted commercial invoice March 2020 which is subsequent to the manufacturing date (12-2019) of trial batches (as per submitted batch analysis report and stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted revised stability studies summary sheets in which test for iron and sucrose are reported separately. • Firm has submitted copy of invoice No. EXP/083/18-19 dated 09-02-2019 for import of 50kg of Iron Sucrose (Batch# ISC190119P5) from M/s Pure Chem Pvt Ltd., in name of M/s Neutro Pharma. However, the invoice is not attested by AD (I&E) DRAP field office. • The firm has submitted another invoice and COA of drug substance from M/s Pure Chem Pvt Ltd., India in which the manufacturing date of API is Jan 2019 which is before the manufacturing date (12-2019) of trial batches • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Revise the label claim as per reference formulation considering the complete salt form along submission of applicable fee**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**
- **Clarification for submitting batch analysis of drug substance from M/s Pure Chem Pvt Limited and details of drug substance manufacturer in section 1.6.5 & 3.2.S.3 of M/s SNJ Labs Pvt. Ltd.,**
- **Calculation for dispensed quantity of API in master formulation**
- **Evidence of availability of atomic absorption spectrophotometer as required by the USP monograph of applied formulation.**
- **Clarification as the batch No. of API (ISC 190119P5) and manufacturer in batch analysis of drug substance is different from that submitted in commercial invoice**

806.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore

	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.30km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6377 dated 08-03-2022
	Details of fee submitted	Rs.50,000/- dated 30-04-2020
	The proposed proprietary name / brand name	**Nal-B 10mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Nalbuphine HCl……..…10mg/ml
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Opioid Analgesic (Morphinan derivatives)
	Reference to Finished product specifications	Neutro's specifications
	Proposed Pack size	1mlx10 ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUBAIN (10.0 mg/mL) 1mL Ampoule Health Canada Approved
	For generic drugs (me-too status)	Buphinal Injection 10mg/ml by Barrett Hodgson Pakistan (Reg# 102934)
	Name and address of API manufacturer.	M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months. (Batches: 0010919, 0020919, 0030919)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Kinz Injection 10mg by M/s Sami Pharma by performing quality tests (Description, identification, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including Accuracy, precision (repeatability, intermediate), linearity, LOD, LOQ, ruggedness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic		
API Lot No.	0010919		
Description of Pack (Container closure system)	A clear to colorless to light straw color solution filled in clear glass printed ampoule of USP type I/ii thermally sealed, laced in plastic tray as 2x5 ampoule and packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	N-002	N-003	N-004
Batch Size	1000 ampoule	1100 ampoule	1100 ampoule
Manufacturing Date	04-2019	05-2019	06-2019
Date of Initiation	28-03-2019	28-03-2019	28-03-2019
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic., valid upto three years from date of inspection. (date of inspection 12-05-2017)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 11month before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.1	• Details of drug substance specifications, analytical procedure and declaration from M/s Rusan Pharma Ltd, Plot No.6406, G.I.D.C., Ankleshawar Dist. Bharuch, Gujarat-393002, India is submitted while drug substance manufacturer is M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic., clarify
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for selecting limits of specific optical rotation test in batch analysis as +160.0 - +142.0 and results as +153.6 by drug product manufacturer instead of -160.0 - -142.0 by drug substance manufacturer • Justification shall be submitted for not performing the test for chloride assay in batch analysis by drug product manufacturer as recommended by drug substance manufacturer

3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted
3.2.P.2	• Justification shall be submitted for not performing the test for extractable volume and particulate matter in pharmaceutical equivalence as recommended by innovator product • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Justification is required for not performing terminal sterilization of applied product
3.2.P.5	• Justification shall be submitted for selecting the limits of pH 4-6 in finished product specifications instead of 3.5-3.7 as recommended by innovator product review document • Reference shall be submitted for selecting the limits of assay test 98-102% in finished product specifications • Justification shall be submitted for not including the test for extractable volume in finished product specifications • Justification shall be submitted for submitted analytical procedure of assay by UV and method validation studies by HPLC • Clarification shall be submitted as you have mentioned *"calculate the percentage of labelled amount of Omeprazole sodium taken by the formula"* in analytical procedure for nalbuphine • Submit results for specificity test in method validation studies • Justification shall be submitted for selecting different limits of pH test 3.0-4.5 in batch analysis of finished product than that submitted in finished product specifications (4-6)
3.2.P.7	• Details for container closure system of drug substance are submitted instead of drug product
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of N-002, N-003 and N-004 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 2L instead of 1100 & 1000 ampoule as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 03-19 in all batches instead of 04-2019 for N-002, 05-2019 for N-003 and 06-2019 for N-004 as mentioned in batch analysis, clarify • Clarification is required as date of initiation of stability study i.e. 28-03-2019 is prior to the manufacturing of trial batches as per submitted batch analysis report • The mobile phase ratio mentioned in raw data sheet is buffer;ACN (70;30) while buffer;ACN (60;40) in analytical method validation, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 03-10-2019 and receiving date is 04-12-2019 which is subsequent to the manufacturing date (3-2019) of trial batches (as per submitted stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March	• The firm submitted that fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022.

	2022. (almost 1 year & 11month before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The gap between date of fee and application submitted is because initially our application was deferred in pre-submission screening of CTD. • The firm has not submitted differential for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F it is mistakenly written while applicant is contract giver.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section), LVP section (Blow, Fill, Seal) and SVP section (Blow, Fill, Seal)
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Rusan Pharma Ltd., Plot No# 6406, G.I.D.C. Estate, Ankleshwar, City; Ankleshwar, Dist., Bharuch-393002 Gujarat State India issued by Food and Drug Control Administration, Gujarat state India valid upto 04-11-2023. The copy of cGMP certificate from a different manufacturer is submitted than that given in form 5F.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted. • However, the batch size of all batches is 2L (2000 ampoule) and the manufacturing date of all batches Batch#001, 002, 003 is

		03-2019 which is contrary to the already submitted data.
3.2.S.1	• Details of drug substance specifications, analytical procedure and declaration from M/s Rusan Pharma Ltd, Plot No.6406, G.I.D.C., Ankleshawar Dist. Bharuch, Gujarat-393002, India is submitted while drug substance manufacturer is M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic., clarify	• The firm submitted that API manufacturer is M/s Rusan Pharma Ltd, and again submitted details of drug substance specifications, analytical procedure from M/s Rusan Pharma Ltd.,
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for selecting limits of specific optical rotation test in batch analysis as +160.0 - +142.0 and results as +153.6 by drug product manufacturer instead of -160.0 - -142.0 by drug substance manufacturer • Justification shall be submitted for not performing the test for chloride assay in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. However, in drug substance specifications, assay by HPLC is mentioned while method of assay by titrimetry is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • The firm has submitted revised batch analysis report of drug substance in which limits of specific optical rotation test has been revised -150.0 to 160.0 and results as -152.82º. • The firm has submitted revised batch analysis report of drug substance in which test for chloride assay has been performed. • COA of drug substance (batch#NLBX018005) from drug substance manufacturer M/s Rusan Pharma has also been submitted
3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted	• Stability study data of drug substance at real time conditions till claimed shelf life is not submitted
3.2.P.2	• Justification shall be submitted for not performing the test for extractable volume and particulate matter in pharmaceutical equivalence as recommended by innovator product • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	• Firm has submitted revised pharmaceutical equivalence studies in which test for extractable volume and particulate matter has been performed. • The firm submitted that we perform pharmaceutical equivalence studies with innovator's product in Pakistan because of unavailability of international innovator's in local market.
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Justification is required for not performing terminal sterilization of applied product	• The firm has submitted revised master formulation containing no overage. • The firm has submitted revised manufacturing flow chart in which terminal sterilization step has been incorporated.

3.2.P.5	• Justification shall be submitted for selecting the limits of pH 4-6 in finished product specifications instead of 3.5-3.7 as recommended by innovator product review document • Reference shall be submitted for selecting the limits of assay test 98-102% in finished product specifications • Justification shall be submitted for not including the test for extractable volume in finished product specifications • Justification shall be submitted for submitted analytical procedure of assay by UV and method validation studies by HPLC • Clarification shall be submitted as you have mentioned *"calculate the percentage of labelled amount of Omeprazole sodium taken by the formula"* in analytical procedure for nalbuphine • Submit results for specificity test in method validation studies • Justification shall be submitted for selecting different limits of pH test 3.0-4.5 in batch analysis of finished product than that submitted in finished product specifications (4-6)	• No justification is submitted. However the firm has submitted revised finished product specifications in which the limits of pH test has been revised as 3.0 to 4.5. • The firm has submitted revised finished product specifications in which the limits of assay test has been revised as 90-110%. • The firm has submitted revised finished product specifications in which test for extractable volume has been included. • The firm has submitted revised analytical method of assay test by HPLC • The firm submitted that it is mistakenly written Omeprazole Sodium instead of Nalbuphine HCl labelled amount and updated analytical procedure is submitted. • Results for specificity test in method validation studies is submitted • The firm has submitted revised batch analysis of finished product in which limits of pH test is as per submitted specifications (3.0 to 4.5)
3.2.P.7	• Details for container closure system of drug substance are submitted instead of drug product	• Details for container closure system of drug product is submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of N-002, N-003 and N-004 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 2L instead of 1100 & 1000 ampoule as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 03-19 in all batches instead of 04-2019 for N-002, 05-2019 for N-003 and 06-2019 for N-004 as mentioned in batch analysis, clarify • Clarification is required as date of initiation of stability study i.e. 28-03-2019 is prior to the manufacturing of trial batches as per submitted batch analysis report	• Firm has submitted copy of invoice No. ANK/18-19/069 dated 12-12-2018 for import of 02kg of Nalbuphine HCl (Batch# NLBX018005) from M/s Rusan Pharma Ltd., in name of M/s Neutro Pharma attested by AD (I&E) DRAP Lahore dated 24-12-2018. • No clarification is submitted. However, revised batch analysis report (COA) of all batches is submitted. As per revised batch analysis report (COA) the batch No# of trial batches is 001, 002, 003, batch size is 2L and manufacturing date of trial batches is 03-2019. • The firm has submitted revised analytical method validation report in which the ratio of mobile phase has been changed as buffer;ACN (70;30). • Firm has submitted another COA of drug substance from drug substance manufacturer and drug product manufacturer in which the manufacturing date of drug substance is

	• The mobile phase ratio mentioned in raw data sheet is buffer;ACN (70;30) while buffer;ACN (60;40) in analytical method validation, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 03-10-2019 and receiving date is 04-12-2019 which is subsequent to the manufacturing date (3-2019) of trial batches (as per submitted stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	09-2018 (batch#NLBXO18005) which is before the manufacturing of trial batches • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Decision: Deferred for submission of following:

- **Differential fee of Rs. 25,000/- for contract manufacturer, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**
- **Clarification for difference in batch size and manufacturing date in BMR and already submitted data**
- **Clarification for mentioning assay by HPLC in drug substance specifications and submitted assay method by titrimetry.**
- **Stability study data of drug substance at real time conditions till claimed shelf life.**
- **Justification shall be submitted for selecting the limits of pH 3.0-4.5 in finished product specifications instead of 3.5-3.7 as per innovator product review document**

807.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.30km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6378 dated 08-03-2022

	Details of fee submitted	Rs.50,000/- dated 30-04-2020
	The proposed proprietary name / brand name	**Nal-B 20mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Nalbuphine HCl……..…20mg/ml
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Opioid Analgesic (Morphinan derivatives)
	Reference to Finished product specifications	Neutro's specifications
	Proposed Pack size	1mlx10 ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUBAIN (20.0 mg/mL) 1mL Ampoule USFDA Approved **Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons****
	For generic drugs (me-too status)	Buphinal Injection 20mg/ml by Barrett Hodgson Pakistan (Reg# 102935)
	Name and address of API manufacturer.	M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months. (Batches: 0010919, 0020919, 0030919)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation

		protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Kinz Injection 20mg by M/s Sami Pharma by performing quality tests (Description, identification, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including Accuracy, precision (repeatability, intermediate), linearity, LOD, LOQ, ruggedness.

STABILITY STUDY DATA

Manufacturer of API	M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic		
API Lot No.	0010919		
Description of Pack (Container closure system)	A clear to colorless to light straw color solution filled in clear glass printed ampoule of USP type I/II thermally sealed, placed in plastic tray as 2x5 ampoule and packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	N-003	N-004	N-005
Batch Size	1000 ampoule	1000 ampoule	900 ampoule
Manufacturing Date	04-2019	05-2019	06-2019
Date of Initiation	28-03-2019	28-03-2019	28-03-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Saneca Pharmaceuticals a.s. Nitrianska 100 92027 Hlohovec Slovak Republic., valid upto three years from date of inspection. (date of inspection 12-05-2017)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 11month before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for selecting limits of specific optical rotation test in batch analysis as +160.0 - +142.0 and results as +153.6 by drug product manufacturer instead of -160.0 - -142.0 by drug substance manufacturer • Justification shall be submitted for not performing the test for chloride assay in batch analysis by drug product manufacturer as recommended by drug substance manufacturer
3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted
3.2.P.2	• Justification shall be submitted for not performing the test for extractable volume and particulate matter in pharmaceutical equivalence as recommended by innovator product • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Justification is required for not performing terminal sterilization of applied product
3.2.P.5	• Justification shall be submitted for selecting the limits of pH 4-6 in finished product specifications instead of 3.5-3.7 as recommended by innovator product review document • Reference shall be submitted for selecting the limits of assay test 98-102% in finished product specifications • Justification shall be submitted for not including the test for extractable volume in finished product specifications

	• Justification shall be submitted for submitted analytical procedure of assay by UV and method validation studies by HPLC • Clarification shall be submitted as you have mentioned *"calculate the percentage of labelled amount of Omeprazole sodium taken by the formula"* in analytical procedure for nalbuphine • Submit results for specificity test in method validation studies • Justification shall be submitted for selecting different limits of pH test 3.0-4.5 in batch analysis of finished product than that submitted in finished product specifications (4-6)
3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of N-003, N-004 and N-005 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 2L instead of 1000 & 900 ampoule as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 03-19 in all batches instead of 04-2019 for N-003, 05-2019 for N-004 and 06-2019 for N-005 mentioned in batch analysis, clarify • Clarification is required as date of initiation of stability study i.e. 28-03-2019 is prior to the manufacturing of trial batches as per submitted batch analysis report • The mobile phase ratio mentioned in raw data sheet is buffer;ACN (70;30) while buffer;ACN (60;40) in analytical method validation, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 03-10-2019 and receiving date is 04-12-2019 which is subsequent to the manufacturing date (3-2019) of trial batches (as per submitted stability summary sheets)* • *Stability data and analytical record is same as presented for other applied strength of 10mg/ml. justification shall be submitted.* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 11month before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The firm submitted that fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. • The gap between date of fee and application submitted is because initially our application was deferred in pre-submission screening of CTD. • The firm has not submitted differential for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F it is mistakenly written while applicant is contract giver.

1.3.5	• GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section), LVP section (Blow, Fill, Seal) and SVP section (Blow, Fill, Seal)
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Rusan Pharma Ltd., Plot No# 6406, G.I.D.C. Estate, Ankleshwar, City; Ankleshwar, Dist., Bharuch-393002 Gujarat State India issued by Food and Drug Control Administration, Gujarat state India valid upto 04-11-2023. The copy of cGMP certificate from a different manufacturer is submitted than that given in form 5F.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted. • However, the batch size of all batches is 2L (2000 ampoule) and the manufacturing date of all batches Batch#001, 002, 003 is 03-2019 which is contrary to the already submitted data.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for selecting limits of specific optical rotation test in batch analysis as +160.0 - +142.0 and results as +153.6 by drug product manufacturer instead of -160.0 - -142.0 by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. However, in drug substance specifications, assay by HPLC is mentioned while method of assay by titrimetry is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.

	• Justification shall be submitted for not performing the test for chloride assay in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	• The firm has submitted revised batch analysis report of drug substance in which limits of specific optical rotation test has been revised -150.0 to 160.0 and results as -152.82º. • The firm has submitted revised batch analysis report of drug substance in which test for chloride assay has been performed. • COA of drug substance (batch#NLBXO18005) from drug substance manufacturer M/s Rusan Pharma has also been submitted
3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted	• Stability study data of drug substance at real time conditions till claimed shelf life is not submitted
3.2.P.2	• Justification shall be submitted for not performing the test for extractable volume and particulate matter in pharmaceutical equivalence as recommended by innovator product • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	• Firm has submitted revised pharmaceutical equivalence studies in which test for extractable volume and particulate matter has been performed. • The firm submitted that we perform pharmaceutical equivalence studies with innovator's product in Pakistan because of unavailability of international innovator's in local market.
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Justification is required for not performing terminal sterilization of applied product	• The firm has submitted revised master formulation containing no overage. • The firm has submitted revised manufacturing flow chart in which terminal sterilization step has been incorporated.
3.2.P.5	• Justification shall be submitted for selecting the limits of pH 4-6 in finished product specifications instead of 3.5-3.7 as recommended by innovator product review document • Reference shall be submitted for selecting the limits of assay test 98-102% in finished product specifications • Justification shall be submitted for not including the test for extractable volume in finished product specifications • Justification shall be submitted for submitted analytical procedure of assay by UV and method validation studies by HPLC • Clarification shall be submitted as you have mentioned *"calculate the percentage of labelled amount of Omeprazole sodium taken by the formula"* in analytical procedure for nalbuphine • Submit results for specificity test in method validation studies	• No justification is submitted. However the firm has submitted revised finished product specifications in which the limits of pH test has been revised as 3.0 to 4.5. • The firm has submitted revised finished product specifications in which the limits of assay test has been revised as 90-110%. • The firm has submitted revised finished product specifications in which test for extractable volume has been included. • The firm has submitted revised analytical method of assay test by HPLC • The firm submitted that it is mistakenly written Omeprazole Sodium instead of Nalbuphine HCl labelled amount and updated analytical procedure is submitted. • Results for specificity test in method validation studies is submitted • The firm has submitted revised batch analysis of finished product in which

	• Justification shall be submitted for selecting different limits of pH test 3.0-4.5 in batch analysis of finished product than that submitted in finished product specifications (4-6)	limits of pH test is as per submitted specifications (3.0 to 4.5)
3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of N-003, N-004 and N-005 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 2L instead of 1000 & 900 ampoule as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 03-19 in all batches instead of 04-2019 for N-003, 05-2019 for N-004 and 06-2019 for N-005 mentioned in batch analysis, clarify • Clarification is required as date of initiation of stability study i.e. 28-03-2019 is prior to the manufacturing of trial batches as per submitted batch analysis report • The mobile phase ratio mentioned in raw data sheet is buffer;ACN (70;30) while buffer;ACN (60;40) in analytical method validation, clarify • *Clarification is required as the manufacturing date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 03-10-2019 and receiving date is 04-12-2019 which is subsequent to the manufacturing date (3-2019) of trial batches (as per submitted stability summary sheets)* • *Stability data and analytical record is same as presented for other applied strength of 10mg/ml. justification shall be submitted.* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of invoice No. ANK/18-19/069 dated 12-12-2018 for import of 02kg of Nalbuphine HCl (Batch# NLBX018005) from M/s Rusan Pharma Ltd., in name of M/s Neutro Pharma attested by AD (I&E) DRAP Lahore dated 24-12-2018. • No clarification is submitted. However, revised batch analysis report (COA) of all batches is submitted. As per revised batch analysis report (COA) the batch No# of trial batches is 001, 002, 003, batch size is 2L and manufacturing date of trial batches is 03-2019. • The firm has submitted revised analytical method validation report in which the ratio of mobile phase has been changed as buffer;ACN (70;30). • Firm has submitted another COA of drug substance from drug substance manufacturer and drug product manufacturer in which the manufacturing date of drug substance is 09-2018 (batch#NLBXO18005) which is before the manufacturing of trial batches • No justification is submitted for submitting same stability data and analytical record as for other applied strength of 10mg/ml. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Decision: Deferred for submission of following:

- **Differential fee of Rs. 25,000/- for contract manufacturer, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**

• **Clarification for difference in batch size and manufacturing date in BMR and already submitted data** • **Clarification for mentioning assay by HPLC in drug substance specifications and submitted assay method by titrimetry.** • **Stability study data of drug substance at real time conditions till claimed shelf life.** • **Justification shall be submitted for selecting the limits of pH 3.0-4.5 in finished product specifications instead of 3.5-3.7 as per innovator product review document**		
808.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 8299 dated 30-03-2022
	Details of fee submitted	Rs.50,000/- dated 25-02-2021
	The proposed proprietary name / brand name	**P-Rox 1ml Ampoule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Piroxicam……..20mg
	Pharmaceutical form of applied drug	I M
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	Neutro's specifications
	Proposed Pack size	1mlx5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PIROXICAM TEVA 20 mg/ 1ml, solution for injection (IM) (ANSM France Approved)
	For generic drugs (me-too status)	Piroxinor 20mg Injection by M/s Nortech Pharmaceuticals (Reg#80001)
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Limited., A-1/2104, phase-III, GIDC, Vapi, Gujarat-396195 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. (Batches; ALC/PCM/131205, ALC/PCM/131206, ALC/PCM/131207)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Mobicam Injection 1ml by M/s Global Pharma by performing quality tests (Description, identification, pH, sterility, BET and assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including precision (repeatability, intermediate), linearity, accuracy, ruggedness, LOD and LOQ.

STABILITY STUDY DATA	
Manufacturer of API	M/s Alcon Biosciences Private Limited., A-1/2104, phase-III, GIDC, Vapi, Gujarat-396195 India
API Lot No.	ALC/PCM/131205
Description of Pack (Container closure system)	A light to yellow color solution, filled in amber glass printed ampoule of USP type I/II, thermally sealed, placed in a honey comb tray as 1x5 ampoules and packed in a unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	5000 ampoules	5000 ampoules	5000 ampoules
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	07-04-2020	07-04-2020	07-04-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Alcon Biosciences Private Limited., A-1/2104, phase-III, GIDC, Vapi – 396195 Dist. Valsad India issued by Food & Drugs Control Administration Gujarat State India valid upto 15-10-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 25-12-2021 while R&I date of submitted application is 30th March 2022. (almost 1 year before R&I date)
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Clarification is required as the manufacturing date mentioned on COA of drug substance by drug substance manufacturer is December 2013 (exp november2018) while manufacturing date mentioned on COA of drug substance by drug product manufacturer is 12-2019 (exp 11-2023) and receiving date 18-03-2020
3.2.P.2	• Details of module 2 are provided in section 3.2.P.2.1 to 3.2.P.2.6, of module 3 clarify • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product
3.2.P.3	• Details of module 2 are provided in section 3.2.P.3.1to 3.2.P.3.4, of module 3 clarify • Justification shall be submitted as the qualitative composition of applied product is not similar to reference product. (**reference product**; Sodium dihydrogen phosphate dihydrate, nicotinamide, alcohol, benzyl alcohol, sodium hydroxide, water for injections, propylene glycol. **Applied product;** Disodium hydrogen phosphate, L-Arginine, Ethanol, benzyl alcohol, sodium metabisulfite, water for injections, propylene glycol**)**
3.2.P.5	• Justification shall be submitted as analytical procedure for assay is submitted as per UV method while method validation studies is submitted as per HPLC method • Justification shall be submitted for not performing test for particulate matter in batch analysis as per submitted specifications
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • *Clarification is required as the manufacturing date of drug substance as per submitted COA is* December 2013 and expiry date is november2018 *which is prior to the manufacturing date (04-2020) of trial batches (as per submitted batch analysis report and stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 25-12-2021 while R&I date of submitted application is 30th March 2022.	• The firm submitted that fee is submitted on 25-12-2021 while R&I date of submitted application is 30th March 2022 and stated that there is only three months difference between fee submission date and R&I date. • The firm has not submitted differential for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of	The firm submitted that in form 5F we have mistakenly submitted that applicant is

	the above (contract giver) in form 5F clarify	manufacturer, actually applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section), LVP section (Blow, Fill, Seal) and SVP section (Blow, Fill, Seal)
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference	• NSAIDs
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit	• Injectable Each ml Contains: Piroxicam……..20mg
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Zeon Health Industries., Plot No# J-201, 202, MIDC, Tarapur, Biosar., Tal Palghar, Dist. Thane, Tarapur-401506 Taluka District Airoli India issued by Food and Drugs Administration (Maharashtra State) India valid upto 04-11-2023. The copy of cGMP certificate from a different manufacturer is submitted than that given in form 5F.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Clarification is required as the manufacturing date mentioned on COA of drug substance by drug substance manufacturer is December 2013 (exp november2018) while manufacturing	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Firm has submitted another COA of drug substance (Batch#PRAH0130218) from a different drug substance manufacturer "M/s Zeon-Health industries" in which manufacturing date mentioned on COA of drug substance by drug substance

	date mentioned on COA of drug substance by drug product manufacturer is 12-2019 (exp 11-2023) and receiving date 18-03-2020	manufacturer is FEB 2018 (Exp; JAN 2023) while manufacturing date mentioned on COA of drug substance by drug product manufacturer is 02-2018 (Exp 01-2023)
3.2.P.2	• Details of module 2 are provided in section 3.2.P.2.1 to 3.2.P.2.6, of module 3 clarify • Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	• Details in section 3.2.P.2.1 to 3.2.P.2.6, of module 3 is not submitted. • The firm submitted that we have performed comparative study of our product with a leading brand of Pakistan Mobicam injection from M/s Sami Pharmaceuticals batch No#20H014, Mfg. date; 01-20 Exp; 01-22. • Revised pharmaceutical report is submitted
3.2.P.3	• Details of module 2 are provided in section 3.2.P.3.1to 3.2.P.3.4, of module 3 clarify • Justification shall be submitted as the qualitative composition of applied product is not similar to reference product. (**reference product**; Sodium dihydrogen phosphate dihydrate, nicotinamide, alcohol, benzyl alcohol, sodium hydroxide, water for injections, propylene glycol. **Applied product;** Disodium hydrogen phosphate, L-Arginine, Ethanol, benzyl alcohol, sodium metabisulfite, water for injections, propylene glycol**)**	• Details in section 3.2.P.3.1to 3.2.P.3.4, of module 3 is not submitted. • Drug-Excipient compatibility study is submitted
3.2.P.5	• Justification shall be submitted as analytical procedure for assay is submitted as per UV method while method validation studies is submitted as per HPLC method • Justification shall be submitted for not performing test for particulate matter in batch analysis as per submitted specifications	• Firm has submitted revised analytical method in which procedure of assay test is submitted as per HPLC method. • Firm has submitted revised batch analysis report in which test for particulate matter is performed
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • *Clarification is required as the manufacturing date of drug substance as per submitted COA is* December 2013 and expiry date is november2018 *which is prior to the manufacturing date (04-2020) of trial batches (as per submitted batch analysis report and stability summary sheets)* • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of commercial invoice No#ZHI-CI/2792 dated 20-03-2018 for import of 25kg of Piroxicam USP (Batch No#PRAH0130218) from M/s Zeon-Health Industries India in name of M/s Neutro Pharma (Pvt.) Ltd. However the invoice is not attested by AD (I&E) DRAP field office. • *No clarification is submitted.* However the firm has submitted another COA from another drug substance manufacturer (Piroxicam USP Batch No#PRAH0130218) from M/s Zeon-Health Industries India in which the expiry date of drug substance is prior to manufacturing of trial batches and batch No. of API is different from that already submitted in dossier. • Record of Digital data logger for temperature and humidity monitoring of

		stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Differential fee of Rs. 25,000/- for contract manufacturer, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**
- **Details in section 3.2.P.2.1 to 3.2.P.2.6, of module 3 of form 5F**
- **Details in section 3.2.P.3.1 to 3.2.P.3.4, of module 3 of form 5F.**
- **Documents for procurement of API with approval from DRAP**

809.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Letter No. F. 1-3/2003-Lic (M-212) dated 14-06-2008 specifying Tablet (General), Tablet (General Antibiotic) Capsule (Cephalosporin), Dry Powder Suspension (Cephalosporin) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6380 dated 08-03-2022
	Details of fee submitted	Rs.50,000/- dated 25-02-2021
	The proposed proprietary name / brand name	**C-Lexin 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefalexin as Monohydrate…….250mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1x12's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	KEFLEX (250mg, 500mg, 750mg) capsule USFDA Approved ***Discontinued****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** Keflex Capsules 250mg MHRA Approved Ceporex Capsules 250mg MHRA Approved
	For generic drugs (me-too status)	Keflex Capsule 250mg by M/s AGP Ltd., (Reg#98686)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batches; F2221/002/2004, F2221/040/2004, F2221/010/2005)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Ceporex capsule 250mg by M/s GSK Pakistan Ltd by performing quality tests (Description, identification, disintegration, assay).

		Firm has submitted CDP results of their product against the product Ceporex capsule 250mg by M/s GSK Pakistan Ltd in water, 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including precision (repeatability, intermediate), linearity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore		
API Lot No.	00214/023/2019		
Description of Pack (Container closure system)	Off white color granular powder filled in blue/blue color capsule and then in printed alu-alu foil and packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	03-02-2020	06-02-2020	10-02-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 11-01-2019 based on inspection conduction on 08-01-2019 and valid upto three years from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note from M/s Pharmagen Limited dated 12/12/2019 for Cephalexin compacted 50kg (Batch No# 00214/023/2019) to M/s Neutro Pharma.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of	Not submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Clarification is required as whether Drug substance follow USP or BP specifications as drug substance manufacturer has submitted specifications and analytical procedure according to both the pharmacopeias. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for not performing the test for pH, specific optical rotation and sulphated ash in batch analysis of drug substance as per BP monograph
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Justification is required for including lactose monohydrate in formulation which is not included in reference product formulation • Justification is required for selecting a single time point of dissolution in CDP studies instead of a minimum of three time-points (zero excluded) for both reference (comparator) and test product as per applicable guideline.
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Outline of method of complete manufacturing operation is not submitted
3.2.P.5	• Justification is required for not including the test for dissolution studies in finished product specifications • Results of analytical method verification studies including accuracy and specificity shall be submitted • Justification is required for assay results of batch No.003 as 1000.33% of cephalexin capsule in batch analysis • Justification is required for not performing the test for dissolution studies in batch analysis of finished product
3.2.P.8	• Justification is required for not performing the test for dissolution studies throughout stability studies • Commercial invoice for the procurement of API shall be submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The firm submitted that fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. The firm submitted that we initially submitted our application on 10-03-2021, but some deficiencies were found in pre submission screening of CTD. • We re-submitted the file on 08-03-2022 along with deficient documents, that's why there is difference between fee submission date and R&I date of application. • The firm has submitted differential fee Rs. 25000/- on deposit slip No#03991636 dated 30-10-2023 for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F we have mistakenly submitted that applicant is manufacturer, actually applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Capsule (Cephalosporin) Section and Dry Powder Suspension (Cephalosporin) Section
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 22-11-2022 based on inspection conduction on 18-11-2022
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted.

3.2.S.4	• Clarification is required as whether Drug substance follow USP or BP specifications as drug substance manufacturer has submitted specifications and analytical procedure according to both the pharmacopeias. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification shall be submitted for not performing the test for pH, specific optical rotation and sulphated ash in batch analysis of drug substance as per BP monograph	• No clarification is submitted • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Firm has submitted revised batch analysis report of drug substance in which test for pH, specific optical rotation and sulphated ash has been performed as per BP monograph
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.2	• Justification is required for including lactose monohydrate in formulation which is not included in reference product formulation • Justification is required for selecting a single time point of dissolution in CDP studies instead of a minimum of three time-points (zero excluded) for both reference (comparator) and test product as per applicable guideline.	• Firm has submitted results of drug excipient compatibility study • No justification is submitted for selecting a single time point of dissolution in CDP studies
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation • Outline of method of complete manufacturing operation is not submitted	• The firm has submitted revised master formulation containing no overage. • Complete manufacturing outline is submitted
3.2.P.5	• Justification is required for not including the test for dissolution studies in finished product specifications • Results of analytical method verification studies including accuracy and specificity shall be submitted • Justification is required for assay results of batch No.003 as 1000.33% of cephalexin capsule in batch analysis • Justification is required for not performing the test for dissolution studies in batch analysis of finished product	• No justification is submitted • Results of analytical method verification studies including accuracy and specificity is submitted • No justification is submitted • No justification is submitted

3.2.P.8	• Justification is required for not performing the test for dissolution studies throughout stability studies • Commercial invoice for the procurement of API shall be submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• No justification is submitted • Firm has submitted copy of sales tax invoice No#1014 dated 19-05-2019 for purchase of 25kg of Cephalexin (compacted) and 25kg Cephalexin (micronized) from M/s Pharmagen Limited in the name of M/s Neutro Pharma (Pvt) Limited. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Justification for selecting a single time point of dissolution in CDP studies instead of a minimum of three time-points (zero excluded) for both reference (comparator) and test product as per applicable guideline.**
- **Justification for not including the test for dissolution studies in finished product specifications**
- **Justification for assay results of batch No.003 as 1000.33% of cephalexin capsule in batch analysis**
- **Justification for not performing the test for dissolution studies in batch analysis of finished product**
- **Justification for not performing the test for dissolution studies throughout stability studies**

810.	Name, address of Applicant / Marketing Authorization Holder	M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Letter No. F. 1-3/2003-Lic (M-212) dated 14-06-2008 specifying Tablet (General), Tablet (General Antibiotic) Capsule (Cephalosporin), Dry Powder Suspension (Cephalosporin) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6379 dated 08-03-2022
	Details of fee submitted	Rs.50,000/- dated 25-02-2021
	The proposed proprietary name / brand name	**C-Lexin 125mg suspension**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension Contains: Cephalexin as Monohydrate…….125mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1x60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceporex Syrup 125mg MHRA Approved
	For generic drugs (me-too status)	Ceporex 125mg/5ml Syrup by M/s GlaxoSmithKline Pakistan., (Reg#003374)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batches; F2221/002/2004, F2221/040/2004, F2221/010/2005)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Ceporex suspension 125mg by M/s GSK Pakistan Ltd by performing quality tests (Description, identification, pH, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including precision (repeatability, intermediate), linearity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore		
API Lot No.	00214/023/2019		
Description of Pack (Container closure system)	Amber glass bottle packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	2000 packs	2000 packs	2000 packs
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	26-02-2020	27-02-2020	28-02-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 11-01-2019 based on inspection conduction on 08-01-2019 and valid upto three years from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note from M/s Pharmagen Limited dated 12/12/2019 for Cephalexin compacted 50kg (Batch No# 00214/023/2019) to M/s Neutro Pharma.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Clarification is required as whether Drug substance follow USP or BP specifications as drug substance manufacturer has submitted specifications and analytical procedure according to both the pharmacopeias. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Justification shall be submitted for using compacted form of API in manufacturing of dry powder suspension • Justification is required as tests for antimicrobial preservative content and efficacy of preservative are not performed
3.2.P.3	• Clarification is required as you have mentioned the use of 1.1% overage in master formulation
3.2.P.5	• Justification is required for selecting limit of assay test in finished product specifications as 95-102% which is different from BP monograph • Results of analytical method verification studies including accuracy and specificity shall be submitted
3.2.P.8	• Commercial invoice for the procurement of API shall be submitted • In use stability study of reconstitution suspension shall be submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. (almost 1 year before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The firm submitted that fee is submitted on 25-02-2021 while R&I date of submitted application is 08th March 2022. The firm submitted that we initially submitted our application on 10-03-2021, but some deficiencies were found in pre submission screening of CTD. • We re-submitted the file on 08-03-2022 along with deficient documents, that's why

		there is difference between fee submission date and R&I date of application. • The firm has submitted differential fee Rs. 25000/- on deposit slip No#6032466225 dated 30-10-2023 for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. **Applicant details:** M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore **Manufacturer details:** M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F we have mistakenly submitted that applicant is manufacturer, actually applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Capsule (Cephalosporin) Section and Dry Powder Suspension (Cephalosporin) Section
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 22-11-2022 based on inspection conduction on 18-11-2022
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted.
3.2.S.4	• Clarification is required as whether Drug substance follow USP or BP specifications as drug substance manufacturer has submitted specifications and analytical procedure according to both the pharmacopeias.	• No clarification is submitted • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed

	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Justification shall be submitted for using compacted form of API in manufacturing of dry powder suspension • Justification is required as tests for antimicrobial preservative content and efficacy of preservative are not performed	• Firm has submitted results of drug excipient compatibility study • Firm has submitted another COA of micronized form of Cephalexin from drug substance manufacturer • No justification is submitted
3.2.P.3	• Clarification is required as you have mentioned the use of 1.1% overage in master formulation	• The firm has submitted revised master formulation containing no overage.
3.2.P.5	• Justification is required for selecting limit of assay test in finished product specifications as 95-102% which is different from BP monograph • Results of analytical method verification studies including accuracy and specificity shall be submitted	• Firm has submitted revised finished product specifications in which limit of assay test has been revised as per BP monograph (80%-120%) • Results of analytical method verification studies including accuracy and specificity is submitted
3.2.P.8	• Commercial invoice for the procurement of API shall be submitted • In use stability study of reconstitution suspension shall be submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of sales tax invoice No#1014 dated 19-05-2019 for purchase of 25kg of Cephalexin (compacted) and 25kg Cephalexin (micronized) from M/s Pharmagen Limited in the name of M/s Neutro Pharma (Pvt) Limited. • Firm has manufactured another trial batch and submitted in use stability study of reconstitution suspension. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Justification for not performing the tests for antimicrobial preservative content and efficacy of preservative**

811.	Name, address of Applicant / Marketing Authorization Holder	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No. 4, Pharma City, 30-Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No. 4, Pharma City, 30-Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-22/2001-Lic (Vol-II) dated 07-06-2021 which specifies Eye Drops Section (General) and Eye Drops Section (Steroid)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No. 1895 dated 20-01-2022
	Details of fee submitted	Rs. 30,000/- dated 24-05-2021 (Deposit slip#3141834076)
	The proposed proprietary name / brand name	Venac Forte 0.3% Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Suspension Contains: Nepafenac…….3mg
	Pharmaceutical form of applied drug	Eye Drops suspension
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	Manufacturer Specifications
	Proposed Pack size	3ml
	Proposed unit price	Rs 665.00/-
	The status in reference regulatory authorities	ILEVRO 0.3%, ophthalmic suspension, USFDA Approved.
	For generic drugs (me-too status)	Curanep Forte Eye Drops by M/s The Schazoo Pharmaceutical, (Reg. No. 107144)
	Name and address of API manufacturer.	M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and justification of specification, container closure system of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Nepatek 0.3% eye drops by M/s Innvotek Pharmaceuticals Islamabad by performing quality tests (Physical appearance, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, accuracy, linearity, precision, robustness, system suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China		
API Lot No.	202080901		
Description of Pack (Container closure system)	LDPE bottles with nozzle and cap of 3ml		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 bottles	2000 bottles	2000 bottles
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	20-10-2020	20-10-2020	20-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted only stability summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted almost 08 months before the R&I date of submitted application.
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both drug substance manufacturer and Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Sterility test for drug substance is not performed in batch analysis by drug product manufacturer as recommended by drug substance manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.S.8	• Stability study data of drug substance from drug substance manufacturer till claimed shelf life is not submitted
3.2.P.	• Submit module 3 drug product part section 3.2.P.1 and 3.2.P.2 as per CTD guidance document • Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, in pharmaceutical equivalence studies • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Justify why complete testing has not been performed in pharmaceutical equivalence studies as per finished product specifications
3.2.P.3	• Justification is required as the manufacturing procedure of the applied product does not contain sterilization process
3.2.P.5	• Justification is required for not including test for benzalkonium chloride identity, benzalkonium chloride assay, edetate disodium identity, edetate disodium assay, osmolality, redispersibility, viscosity, particle size distribution and endotoxin content in finished product specification as recommended by innovator product review document. • The limit of pH test (pH 7.0-8.0) is different than that recommended by innovator product review document (pH 6.8). • The results of assay test are more than that recommended by innovator product review document (7.75, 7.69, 7.72)

	• Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not included in specification
3.2.P.6	• COA of secondary reference standard is submitted from M/s Precise Chem Pharma Pvt. Ltd India while drug substance manufacturer as per section 3.2.S.2 is M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China, Clarify
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP • Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA is not submitted • Justification is required as the stability study has not been performed as per the stability conditions recommended by ICH Q1A (R2) 2.2.7.3. for Drug products packaged in semipermeable containers • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not performed in stability studies • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted

Previous Decision (M-326-DRB): Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting for reply.

Response of firm:

Section	Deferment Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted almost 08 months before the R&I date of submitted application.	• The firm submitted that fee was deposited when dossier was completed at our end and sent for screening. But during screening process, we were informed regarding some short comings. So, we worked on it to provide the required data and it took time. So this is the reason that there is gap between fee deposit date and R&I of submitted application
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted a request letter to Deputy Director General DRAP Lahore for the condution of HMP inspection dated 28-03-2022.
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	• Not submitted
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both drug substance manufacturer and Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both drug substance manufacturer and Drug product manufacturer is submitted. • Analytical Method Verification studies including accuracy, repeatability (method precision),linearity, solution stability and system suitability is

	manufacturer for drug substance shall be submitted. • Sterility test for drug substance is not performed in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	submitted. However, results of specificity test is not submitted. • Sterility test results for drug substance is submitted by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary reference standard including source and lot number is submitted
3.2.S.8	• Stability study data of drug substance from drug substance manufacturer till claimed shelf life is not submitted	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
3.2.P.	• Submit module 3 drug product part section 3.2.P.1 and 3.2.P.2 as per CTD guidance document • Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, in pharmaceutical equivalence studies • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Justify why complete testing has not been performed in pharmaceutical equivalence studies as per finished product specifications	• Module 3 drug product part section 3.2.P.1 and 3.2.P.2 is submitted • Details of comparator product including batch numbers, manufacturing & expiry date is submitted. • The firm submitted that innovator product is not available in Pakistan while comparator product is availbale in pakitan, so we compared our prodct with Nepatek 0.3% ophthalmic suspension • The firm submitted that description (physical appearance), pH and assay are main parameters in testing of ophthalmic suspension, so these have been performed in pharmaceutical equivalence studies.
3.2.P.3	• Justification is required as the manufacturing procedure of the applied product does not contain sterilization process	• The firm submitted that bottles with nozzles and caps are sterilized by gamma radiation. All manufacturing process are carried out under aseptic conditions • Nepafenac is available in sterilized form • Carbomer 974, guar gum and carboxymethyl cellulose sodium are mixed in water and sterilized by heating in autoclave. • Remaining excipient are mixed in purified water and sterilized by passing through 0.22 micron filter. • Final mixing tank is sterilized by steam • All the above materials are collected in final mixing tank and are mixed in final mixing tank under aseptic conditions. • Filling process is completed under aseptic conditions. • So no further sterilization is required after filling of bottles under aseptic conditions
3.2.P.5	• Justification is required for not including test for benzalkonium chloride identity,	• The firm submitted that benzalkonium chloride and edetate disodium are

	benzalkonium chloride assay, edetate disodium identity, edetate disodium assay, osmolality, redispersibility, viscosity, particle size distribution and endotoxin content in finished product specification as recommended by innovator product review document. • The limit of pH test (pH 7.0-8.0) is different than that recommended by innovator product review document (pH 6.8). • The results of assay test are more than that recommended by innovator product review document (7.75, 7.69, 7.72) • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not included in specification	excipients, their complete analysis is conducted in raw material form. While in finished form of eye drops our claim is only for active material i.e. Nepafenac 3mg/ml. identification and assay tests of excipients are not required when they are added in formulation. Only testing and analysis of active material is conducted in finished product of eye drops. • Tests for osmolality, redispersibility, viscosity and particle size distribution will be included when commercial batches of full scale are prepared. • Bacterial Endotoxin Test is not included in finished product analysis of eye drops. Only sterility test is included • The firm submitted that the product is stable at pH between 7.0 to 8.0 with regard to colour of the product and stability of pH. Physical appearance of the product changes from yellow to orange at pH below 7.0 • Moreover we are already manufacturing Nepafenac 0.1% ophthalmic suspension with pH range of 7.0 to 8.0. this product is well stable at this pH range. • The firm submitted that assay limit of applied product is 90 to 110% of label claim. Assay results are well within this limit • SOP for tests for antimicrobial preservative and efficacy of preservative have been prepared and submitted
3.2.P.6	• COA of secondary reference standard is submitted from M/s Precise Chem Pharma Pvt. Ltd India while drug substance manufacturer as per section 3.2.S.2 is M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China, Clarify	• The firm submitted that their QA department has approved three sources for procurement of Nepafenac. These include; Hangzhou Zhongchang Scientific Co., China, Henan Purui Pharma China and Precise ChemiPharma India. • The working standard was available manufactured by Precise Chemipharma india. That is good thing that the raw material and working standard used were of different companies
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP • Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA is not submitted • Justification is required as the stability study has not been performed as per the stability conditions recommended by ICH Q1A (R2) 2.2.7.3. for Drug products packaged in semipermeable containers	• The firm submitted that as we are already manufacturing Nepafenac 0.1% eye drops with DRAP registered name of Venac 0.1% eye drops. The material is always available in our raw material store. So we have not got DRAP approval for procurement of active or raw material to prepare trial batches of Nepafenac 0.3 eye drops. • K • The firm submitted that our product is not packaged in semipermeable

	• Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not performed in stability studies • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	containers. So stability study of the product was not performed as per conditions of drug product packaged in semipermeable containers • SOP for determination of antimicrobial preservative content prepared and testing will be performed on commercial batches used for stability study. • The firm submitted that we analyzed the product on HPLC manufactured by Skyam Germany. Audit trial is not available on this instrument • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years**
- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin**
- **Results of specificity test in method verification of studies drug substance**
- **Justification for not including test for benzalkonium chloride identity, benzalkonium chloride assay, edetate disodium identity, edetate disodium assay, osmolality, redispersibility, viscosity, particle size distribution and endotoxin content in finished product specification as per innovator product review document.**
- **Clarification for submitting COA of secondary reference standard from M/s Precise Chem Pharma Pvt. Ltd India while drug substance manufacturer as per section 3.2.S.2 is M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China**
- **Submit documents for the procurement of API with approval from DRAP**
- **Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA.**
- **Justification as the stability study has not been performed as per the stability conditions recommended by ICH Q1A (R2) 2.2.7.3. for Drug products packaged in semipermeable containers**
- **Justification as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not performed in stability studies**

812.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018 which specifies Tablet section (General/Antibiotic)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical	☐ Domestic sale

	product	☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3728 dated 09/02/2022
	Details of fee submitted	PKR 30,000/-: dated 15/09/2021 (Deposit Slip#675681277631)
	The proposed proprietary name / brand name	**Empawrd-M 5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (In-House)……..……5mg Metformin HCl (USP)…….……...500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5 mg/1000 mg) film-coated tablet USFDA approved
	For generic drugs (me-too status)	Xenglu-Met 5/500mg Tablets by M/s Hilton Pharma (Reg#105290)
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fumeng County, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410029, MEF/1410028, MEF/1410027) **Empagliflozin:**

		Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20160606, 20161017, 20161219)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Empaa-M 5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). CDP has been performed against the same brand that is Empaa M 5/500 mg Tablet by M/s Weatherfolds Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted summary of analytical method validation studies including linearity, range, accuracy, precision, LOD, LOQ.

STABILITY STUDY DATA			
Manufacturer of API	**<u>Empagliflozin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India		
API Lot No.	**Metformin HCl:** MEF/18091912 **Empagliflozin:** E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Alu-Alu Blister packed in bleech card box		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	900 tab	900 tab	900 tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	11/08/2020	11/08/2020	11/08/2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued	**<u>Empagliflozin:</u>** Firm has submitted copy of GMP certificate in the name

	by concerned regulatory authority of country of origin.	of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fuxin City, Liaoning Province - 123000, China issued by Fuxin Food and Drug Administration China valid upto 27-09-2020. Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., China valid upto 20-12-2022. **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 09-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice No. HN190108-C dated 08-01-2019 for import of 0.41Kg of Empagliflozin (Batch No# E-20181027-D02-E06-01) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. Firm has also submitted copy of form 6 dated 23-01-2019 for import of 0.41Kg of Empagliflozin in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/1678/18-19 dated 21-11-2018 for import of 500Kg of Metformin HCl (Batch No# MEF/18091912) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 05-12-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, summary data sheets etc. Raw data sheets and COAs are not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of cGMP certificate issued on 10-06-2022 based on inspection conducted on 30-03-2022
1.4.1.	• The applied drug product is a generic drug product while you have applied for a new drug product, clarify	• Firm has corrected the application type in form 5F as Generic drug product
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for Empagliflozin and Metformin issued by relevant regulatory authority of country of origin is required • Address of M/s Aarti drugs Limited in	**Empagliflozin:** The firm has submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Empagliflozin confirming that

	submitted application is different than that mentioned in GMP certificate, clarify	the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Firm has also submitted copy of DML (License#Liao20150233) of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China valid upto 17-11-2027 verified from NMPA website. **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. *The certificate is valid till 19-03-2023*
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.3	• Submit details in this section as per the guidance document	• Details in this section are submitted as per guidance document
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by Drug Product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Metformin HCl and Empagliflozin shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP. • Justification is required for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is not submitted. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by Drug Product manufacturer is not submitted. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin by Drug Product manufacturer is not submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Metformin HCl and Empagliflozin is submitted • *No response submitted* • *No response submitted* • *No response submitted* • Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies from Drug Substance manufacturer is submitted. However, the batch No# (MEF/19040649) of Metformin HCl is different from that mentioned in batch analysis of drug product manufacturer.

	• Justification is required for not performing test for identification and residue on ignition for drug substance empagliflozin in batch analysis by drug product manufacturer as recommended by drug substance manufacturer. • Provide Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.	
3.2.P.2	• Justify why Pharmaceutical equivalence and CDP of the applied product has not been performed against the innovator product? • Submit detailed CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters used and f2 factor calculation	• Firm has again submitted Pharmaceutical Equivalence of applied product against the brand that is Empaa-M 5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). • Firm has submitted details of CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters. *However CDP has been performed against the comparator product Empaa-M 5/500mg tablet by M/s Weatherfolds Pharmaceuticals.*
3.2.P.5	• Justification is required for not including the test for assay in finished product specifications • Detailed analytical procedures used for testing the drug product shall be provided. • Complete analytical method validation studies including specificity test shall be submitted • Justification is required for not performing test for uniformity of dosage units (content uniformity/weight variation) in batch analysis as recommended by innovator product review document • Submit readable copies of batch analysis report of three batches	• Firm has submitted revised finished product specifications containing content uniformity test, time point for dissolution studies and details of assay test. • Firm has submitted detailed analytical procedures used for testing the drug product shall be provided • Firm has submitted analytical method validation studies including results of specificity test. • Firm has submitted copy of revised batch analysis report containing results of content uniformity test
3.2.P.6	Clarification is required whether the same Reference Standards or Materials of empagliflozin was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials is 18.04.2018 while manufacturing date of drug product as per submitted COA is 08-2020	• Firm has not submitted any clarification. However, Firm has submitted COA of another working standard. The expiry date mentioned on this reference standard is 05-08-2020 and manufacturing of trial batches is subsequent to this date.
3.2.P.8	• Submit complete analytical record of stability study including summary data sheets, COA, Raw data sheets, and chromatograms. Chromatograms of accelerated stability study are attached with summary sheet of real time study and vice versa • Compliance Record of HPLC software	• Firm has submitted analytical record of stability study including summary data sheets, COA. *However detailed Raw data sheets and chromatograms are not submitted* • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

	21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Previous Decision (M-330-DRB): Deferred for submission of following:

- Valid GMP certificate / DML of drug substance manufacturer for Metformin issued by relevant regulatory authority of country of origin
- Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer.
- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl and Empagliflozin by Drug Product manufacturer.
- Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as per USP monograph.
- Justification for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as per USP monograph
- Justification for not performing test for identification and residue on ignition for drug substance Empagliflozin in batch analysis by drug product manufacturer as recommended by drug substance manufacturer.
- Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.
- Pharmaceutical equivalence and CDP of the applied product against the innovator product
- Clarification whether the same Reference Standards or Materials of empagliflozin was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials is 18.04.2018 while manufacturing date of trial batches is subsequent to this date.
- Detailed Raw data sheets and chromatograms are not submitted
- Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Firm's Response:

S No	Observations	Response by firm
1	• Valid GMP certificate / DML of drug substance manufacturer for Metformin issued by relevant regulatory authority of country of origin	• The firm has submitted copy of cGMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., at & post Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India valid upto 20-06-2026
2	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is submitted
3	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl and Empagliflozin by Drug Product manufacturer.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl and Empagliflozin by drug product manufacturer is submitted.
4	• Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as per USP monograph.	• No clarification is submitted

5	• Justification for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as per USP monograph	• Firm has submitted revised batch analysis report for drug substance Metformin HCl in which test for identification (Reaction of Chloride) and residue on ignition is performed by drug product manufacturer
6	• Justification for not performing test for identification and residue on ignition for drug substance Empagliflozin in batch analysis by drug product manufacturer as recommended by drug substance manufacturer.	• Firm has submitted revised batch analysis report for drug substance empagliflozin in which test for identification and residue on ignition is performed by drug product manufacturer
7	• Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.	• Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies from Drug Substance manufacturer is submitted. However, the batch No# (MEF/19040649) of Metformin HCl is different from that mentioned in batch analysis and stability summary sheets of drug product manufacturer
8	• Pharmaceutical equivalence and CDP of the applied product against the innovator product	• Firm has again submitted Pharmaceutical Equivalence and CDP studies of applied product against the brand that is Empaa-M 5/500mg tablet by M/s Weatherfolds Pharma.
9	• Clarification whether the same Reference Standards or Materials of empagliflozin was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials is 18.04.2018 while manufacturing date of trial batches is subsequent to this date.	• Firm has not submitted any clarification. However, firm has submitted another COA of Reference Standards or Materials of empagliflozin and the expiry date mentioned on the COA of Reference Standards or Materials is 05.08.2020
10	• Detailed Raw data sheets and chromatograms are not submitted	• Chromatograms for Empa-Metformin 12.5/500mg Tablet strength is submitted • Detailed Raw data sheets of stability testing is not submitted, instead chromatograms of other strenght are submitted
11	• Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	• Fee for correction/pre-approval change is not submitted

Previous Decision (M-331st-DRB): Deferred for submission of:

- Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead
- Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.
- COA of Reference Standards or Materials of empagliflozin was used for test and analysis of drug product in stability study
- Detailed Raw data sheets and chromatograms of stability study of applied product
- Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Firm's Response:

S No	Deferment Reason	Response by firm

1	• Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead	• The firm has submitted response from drug substance manufacturer M/s Aarti Drugs Limited India. The firm has submitted that Metformin Hydrochloride Batch No. MEF/18091912 manufactured in Sep-2018 and USP assay by HPLC method incorporated in USP monograph on Nov 2019. At the time Sep-2018 Assay by HPLC method was not available in USP Monograph at the time of release of batch. • In the previous version USP monograph upto Nov-2019 Assay by potentiometry method was going on hence Assay analysis for Metformin Hydrochloride Batch No. MEF/18091912 was performed by potentiometry.
2	• Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.	• Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer is submitted
3	• COA of Reference Standards or Materials of empagliflozin was used for test and analysis of drug product in stability study	• The firm submitted that having initially utilized the working standard with batch#E6DZ201802, manufactured on 06-08-2018 and expiring on 05-08-2020, we later proceeded to meticulously develop our proprietary reference standard from the same raw material, resulting in a refined benchmark for further stability analysis. The COA of Reference Standards or Materials of empagliflozin is submitted
4	• Detailed Raw data sheets and chromatograms of stability study of applied product	• Firm has submitted data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA and summary data sheets.
5	• Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	• Firm has submitted fee Rs. 7,500/- vide deposit slip#60216368985 for correction/pre-approval change in product specifications

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

813.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 16112 dated 10-06-2021
	Details of fee submitted	Rs.20,000/- dated 03-05-2021
	Proposed proprietary name/brand name	Gludap 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Xiga 5mg Tablets by M/s CCL Pharmaceuticals (Reg#090504)
	GMP status of the Finished product manufacturer	GMP certificate issued to firm on 21st May 2019, based on inspection conducted on 23-04-2019 & valid upto 22-4-20222
	Name and address of API manufacturer.	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has submitted summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability study is conducted at 40 ^{O} ± 2 ^{O}C /75% ± 5% RH for 6 months. The real time stability study is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 36 months. (Batch No. 130401, 130402 & 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures and its verification studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been performed against innovator product Forxiga 5mg tablet. CDP has been performed against innovator product Forxiga 5mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies is submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.		
API Lot No.	DGF-201902001		
Description of Pack (Container closure system)	Alu/Alu Blister Packing		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	DPT-001	DPT-002	DPT-003
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	08-01-2020	08-01-2020	08-01-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted copy of minutes of 296th meeting of registration board dated 8th, 9th & 10th September, 2020 in which their product Empaglif 10mg and 25mg applied on form 5F has been approved based on the inspection conducted by the panel for authenticity of stability data

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm submitted copy of GMP certificate of Jiangsu Yongan Pharmaceutical Co., Ltd China valid up to 03-03-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate and form 6 attested by Assistant Director (I&E) DRAP Islamabad dated 01-04-2019 for the import of 200gm Dapagliflozin Propanediol Monohydrate and 5mg impurity A and 5mg Impurity B. However, the firm has not submitted invoice for import of said materials.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit Valid copy of Drug Manufacturing License	The firm have submitted valid Drug Manufacturing License
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	The firm submitted valid GMP certificate
3.2.S.4.1. - 3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Firm have submitted Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. However, the chromatographic test conditions were different as compared with drug substance manufacturer. For example, the chromatographic conditions used by the **drug substance manufacturer are:** **Related substances:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;50v/v) DetectIion; 225nm Injection; 20ul Flow rate; 1ml/min **Drug product manufacturer;** **Related substances:** Mobile phase; Methanol:Water (70;30 v/v) Detectio; 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC **Drug substance manufacturer:** **Assay:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v)

		Detection; 225nm Injection; 20ul Flow rate; 1ml/min Temperature: 25ºC **Drug product manufacturer;** **Assay:** Mobile phase; Methanol:Water (70;30 v/v) Detection; 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC
3.2.S.4.3	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	The firm have submitted Analytical Method validation studies performed by the Drug Product manufacturer for drug substance(s)
3.2.S.4.4	• In batch analysis of drug substance performed by drug product manufacturer, in test for identification you have submitted that it is positive for empagliflozin while the applied product is dapagliflozin, clarify? • Justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (propanediol, residue on ignition, heavy metals, related substances, residual solvents, particle size)	• The firm submitted that during analysis Dapagliflozin was identified. *However due to typo-graphical error Empagliflozin was written instead of dapagliflozin in COA. The rectified COA with supportive documents is submitted*. • No justification provided for incomplete analysis
3.2.P.1	• You have used lactose monohydrate in your formulation while innovator product has used lactose anhydrous. Justify that the applied product is equivalent to innovator product.	The firm submitted that we designed formulation qualitatively similar to innovator (Forxiga tablet). *We actually used lactose anhydrous and was mistakenly written as lactose monohydrate. The firm have submitted revised BMR.*
3.2.P.4	• In control of excipients you have given specifications for croscarmellose while you have not used croscarmellose in formulation, clarify? Moreover, you have used lactose monohydrate while you have not provided specifications of lactose monohydrate?	The firm submitted that it was mistakenly written, specifications for lactose anhydrous is submitted
3.2.P.8.1	• Stability data of drug product at initial time point is not submitted • You have mentioned in house specifications in module I section 1.5.6 while innovators specifications in stability summary sheets, clarify?	• Stability data of drug product at initial time point is submitted • The firm submitted that they have designed their product on innovator's specifications and updated the specifications at section 1.5.6. as innovator's specifications without submission of applicable fee. The firm also submitted revised form 5F
	• Submit invoice for the imported raw materials. • Submit Compliance Record of HPLC software 21CFR	• The firm have not submitted invoice for the imported raw material • The firm submitted A General Compliance certificate of HPLC software 21CFR

	• Provide complete calculation for determining the quantity of dispensed drug substance keeping in view water content	• The firm have submitted calculation for determining the quantity of dispensed drug substance on theoretical basis. *The water content was not kept in mind while making calculation for dispensing drug substance*

Previous Decision (M-316-DRB) : Deferred for following:

- Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer
- Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.
- Clarification for not considering the water content while making calculation for dispensing of drug substance
- Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Evaluation by PEC:

Deferment reasons	**Response**
• Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer	The firm submitted that testing of propanediol contents were not performed due to unavailability of GC. In future testing will be done through 3rd party i.e. M/s Rotex Pharmaceuticals and submitted copy of agreement for contract testing of raw materials
• Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.	The firm has submitted revised DMF of drug substance manufacturer from drug substance manufacturer and chromatographic conditions of drug substance manufacturer and drug product manufacturer are same. The firm further stated that this source of API have been used for the manufacturing of product for stability batches. The previous DMF has been mistakenly submitted in the dossier
• Clarification for not considering the water content while making calculation for dispensing of drug substance	The firm submitted that Water contents are already calculated in factor calculation
• Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted fee Rs. 7500/- on deposit slip# 09840920132 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Previous Decision (M-329th-DRB): Deferred for submission of following:

- Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.
- Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.

Firm's Response:

Deferment reasons	**Firm's Response**
• Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.	• The firm submitted that we have submitted the contract agreement for the outsource testing of drug substance from M/s Rotex Pharma unless and until our QC Labbs equipped with GC to test the Dapagliflozin • DRAP notification of contract manufacturing dated 15-10-2021 is submitted for reference
• Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.	• The firm has submitted analytical procedure of drug substance with trail revision from drug substance manufacturer

Decision: The board deliberated the rule 20 A (1) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and directed the Division of PE & R to bring the matter of contract analysis along with the SOP containing the technical and legal explainations and procedure of grant of permission of contract analysis for the consideration of the Registration Board.		
814.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 16113 dated 10-06-2021
	Details of fee submitted	Rs.20,000/- dated 03-05-2021
	The proposed proprietary name / brand name	Gludap 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…10mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Dapa 10mg Tablet by M/s Hilton Pharma (Reg#089368)
	GMP status of the Finished product manufacturer	GMP certificate issued to firm on 21st May 2019, based on inspection conducted on 23-04-2019 and valid upto 22-04-20222
	Name and address of API manufacturer.	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		The firm has submitted summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability study is conducted at 40 ^{O} ± 2 ^{O}C /75% ± 5% RH for 6 months. The real time stability study is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 36 months. (Batch No. 130401, 130402 & 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures and its verification studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been performed against innovator product Forxiga 10mg tablet. CDP has been performed against innovator product Forxiga 10mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies is submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.
API Lot No.	DGF-201902001
Description of Pack (Container closure system)	Alu/Alu Blister Packing
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	DPT-004	DPT-005	DPT-006
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	13-01-2020	13-01-2020	13-01-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted copy of minutes of 296th meeting of registration board dated 8th, 9th & 10th September, 2020 in which their product Empaglif 10mg and 25mg applied on form 5F has been approved based on the inspection conducted by the panel for authenticity of stability data
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm submitted copy of GMP certificate of Jiangsu Yongan Pharmaceutical Co., Ltd China valid up to 03-03-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate and form 6 attested by Assistant Director (I&E) DRAP Islamabad dated 01-04-2019 for the import of 200gm Dapagliflozin Propanediol Monohydrate and 5mg impurity A and 5mg Impurity B. However, the firm has not submitted invoice for import of said materials.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit Valid copy of Drug Manufacturing License	The firm have submitted valid Drug Manufacturing License
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	The firm submitted valid GMP certificate
3.2.S.4.1 . - 3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Firm have submitted Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. However, the chromatographic test conditions were different as compared with drug substance manufacturer.

		For example, the chromatographic conditions used by the **drug substance manufacturer are:** **Related substances:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v) Detector 225nm Injection; 20ul Flow rate; 1ml/min **Drug product manufacturer;** **Related substances:** Mobile phase; Methanol:Water (70;30 v/v) Detector 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC **Drug substance manufacturer:** **Assay:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v) Detector 225nm Injection; 20ul Flow rate; 1ml/min Temperature: 25ºC **Drug product manufacturer;** **Assay:** Mobile phase; Methanol:Water (70;30 v/v) Detector 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	The firm have submitted Analytical Method validation studies performed by the Drug Product manufacturer for drug substance(s)
3.2.S.4.4	• In batch analysis of drug substance performed by drug product manufacturer, in test for identification you have submitted that it is positive for empagliflozin while the applied product is dapagliflozin, clarify? • Justification shall be provided for any incomplete analyses of the drug substance/API by Drug Product manufacturer (propanediol, residue on ignition, heavy metals, related substances, residual solvents, particle size)	• The firm submitted that during analysis Dapagliflozin was identified. *However due to typo-graphical error Empagliflozin was written instead of dapagliflozin in COA. The rectified COA with supportive documents is submitted*. • No justification provided for incomplete analysis
3.2.P.1	• You have used lactose monohydrate in your formulation while innovator product has used lactose anhydrous. Justify that the applied product is equivalent to innovator product.	The firm submitted that we designed formulation qualitatively similar to innovator (Forxiga tablet). *We actually used lactose anhydrous and was mistakenly written as lactose monohydrate. The firm have submitted revised BMR.*

3.2.P.2.2.1	The batch number of innovator product Forxiga 10mg tablet mentioned in Pharmaceutical equivalence report is 132642 while the batch number mentioned in comparative dissolution report is NX101. Clarify that which batch number product was used in both the studies	The batch No. of innovator product Forxiga 10mg tablet taken in Pharmaceutical equivalence report is NX101. Submitted chromatogram too is written with batch No. NX101. *It was a typo error in report. Corrected repot is submitted.*
3.2.P.4	• In control of excipients you have given specifications for croscarmellose while you have not used croscarmellose in formulation, clarify? Moreover, you have used lactose monohydrate while you have not provided specifications of lactose monohydrate?	It was mistakenly written, specifications for lactose anhydrous is submitted
3.2.P.5.2	• The Mobile phase composition in assay test is not mentioned in analytical procedure?	Method for analysis of drug product is submitted along with chromatographic conditions / mobile phase composition in assay analysis
3.2.P.8.1	• Stability data of drug product at initial time point is not submitted • Stability summary sheet for accelerated and real time stability data at 6th month time point is not submitted • You have mentioned in house specifications in module I section 1.5.6 while innovators specifications in stability summary sheets, clarify?	• Stability data of drug product at initial time point is submitted • Stability summary sheet for accelerated and real time stability data at 6th month time point is submitted • The firm submitted that they have designed their product on innovator's specifications and updated the specifications at section 1.5.6. as innovator's specifications without submission of applicable fee. The firm also submitted revised form 5F
	• Submit invoice for the imported raw materials. • Submit Compliance Record of HPLC software 21CFR • Provide complete calculation for determining the quantity of dispensed drug substance keeping in view water content	• The firm have not submitted invoice for the imported raw material • The firm submitted A General Compliance certificate of HPLC software 21CFR • The firm have submitted calculation for determining the quantity of dispensed drug substance on theoretical basis. *The water content was not kept in consideration while making calculation for dispensing drug substance*

Previous Decision (M-316-DRB) : Deferred for following:

- Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than drug substance manufacturer.
- Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer
- Clarification for not considering the water content while making calculation for dispensing of drug substance
- Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Evaluation by PEC:

Deferment reasons	**Response**
• Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer	The firm submitted that testing of propanediol contents were not performed due to unavailability of GC. In future testing will be done through 3rd party i.e. M/s Rotex Pharmaceuticals and submitted copy of agreement for contract testing of raw materials

• Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.	The firm has submitted revised DMF of drug substance manufacturer from drug substance manufacturer and chromatographic conditions of drug substance manufacturer and drug product manufacturer are same. The firm further stated that this source of API have been used for the manufacturing of product for stability batches. The previous DMF has been mistakenly submitted in the dossier
• Clarification for not considering the water content while making calculation for dispensing of drug substance	The firm submitted that Water contents are already calculated in factor calculation
• Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted fee Rs. 7500/- on deposit slip# 433726858656 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Previous Decision (M-329th-DRB): Deferred for submission of following:

- Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.
- Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.

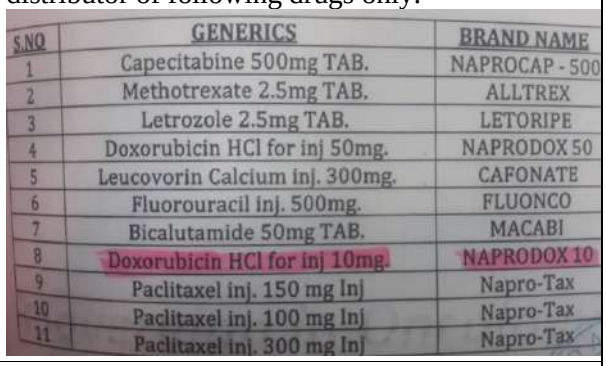
Firm's Response:

Deferment reasons	**Firm's Response**
• Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.	• The firm submitted that we have submitted the contract agreement for the outsource testing of drug substance from M/s Rotex Pharma unless and until our QC Labbs equipped with GC to test the Dapagliflozin • DRAP notification of contract manufacturing dated 15-10-2021 is submitted for reference
• Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.	• The firm has submitted analytical procedure of drug substance with trail revision from drug substance manufacturer

Decision: The board deliberated the rule 20 A (1) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and directed the Division of PE & R to bring the matter of contract analysis along with the SOP containing the technical and legal explainations and procedure of grant of permission of contract analysis for the consideration of the Registration Board.

Case No. 13: Deferred Priority Registration application as per Decision of 257th meeting of DRB on Form 5F (Import)

815.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot #81, block B, S.M.C.H.S., Karachi.
	Details of Drug Sale License of importer	**DSL No**.: 1245 **Address**: Al-Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** 1. Plot No. 10 Sector 25 KIA Karachi 2. HT-8, Landhi Industrial Area, Karachi **Validity:** 18/05/2022 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Thane–401506, Mahrashtra State India.

	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd., G-17/1, M.I.D.C. Tarapur, Boisar, Distt – Thane – 401506 India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COPP/CERT/KD/83867/2019/11/27845/143336 dated 02/05/2019 issued by Food and Drug Administration Mahrashtra State Mumbai India for Doxorubicin Hydrochloride for Injection BP 10mg (lyophilszed). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The CoPP is valid upto 03/04/2022. The name of importing country mentioned on annexure attached with CoPP is mentioned as Pakistan. **GMP:** Firm has submitted notarized copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 dated 04/04/2019 issued by Food and Drug Administration Mahrashtra Estate Mumbai India The GMP certificate is valid upto 03/04/2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of letter of authorization from M/s Naprod Life Sciences Pvt. Ltd 304, Town Centre-1, Andheri Kurla Road, Andheri (East), Mumbai, India., The letter species that the manufacturer authorizes M/s Al Habib Pharmaceuticals, Plot #81, block B, SMCHS., 74400 Karachi., Pakistan as sole agent and distributor of following drugs only. 
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

S.NO	GENERICS	BRAND NAME
1	Capecitabine 500mg TAB.	NAPROCAP - 500
2	Methotrexate 2.5mg TAB.	ALLTREX
3	Letrozole 2.5mg TAB.	LETORIPE
4	Doxorubicin HCl for inj 50mg.	NAPRODOX 50
5	Leucovorin Calcium inj. 300mg.	CAFONATE
6	Fluorouracil inj. 500mg.	FLUONCO
7	Bicalutamide 50mg TAB.	MACABI
8	Doxorubicin HCl for inj 10mg.	NAPRODOX 10
9	Paclitaxel inj. 150 mg Inj	Napro-Tax
10	Paclitaxel inj. 100 mg Inj	Napro-Tax
11	Paclitaxel inj. 300 mg Inj	Napro-Tax

	Dy. No. and date of submission	Dy. No. 5228: dated; 24-02-2022
	Details of fee submitted	PKR 150,000 ; Dated: 26-01-2022 (Deposit slip#976636166)
	The proposed proprietary name / brand name	**NAPRODOX 10mg lyophilized powder for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Doxorubicin HCl ……. 10 mg
	Pharmaceutical form of applied drug	Lyophilized powder for Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic and Immunomodulating Agents; Anthracyclines and related substances WHO ATC Code: L01DB01
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Doxorubicin Hydrochloride 10mg/vial for Injection by M/s Hikma USFDA Approved
	For generic drugs (me-too status)	Astrodox Lyophilized Powder for Injection 10mg by M/s Aster Life Sciences (Reg. No# 78110)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated study is conducted at 40±2°C/75± 5%RH for 6 months and the real time stability study is conducted at 25 ± 2°C/ 60 ± 5 % RH till 24 months. (Batches: 71203715, 71204715, 71204915)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing

		process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product ADRIAMYCIN RD 10 mg/vial injection by performing quality tests (Description, Identification, pH, Assay, particulate matter, reconstitution time).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, precision, linearity and range, accuracy and solution stability for the applied product.
	Container closure system of the drug product	5ml 20mm Flint Tubular-USP Type-I Glass vial with Rubber stopper 20mm Grey Bromo Butyl Slotted Siliconised by Silicon & Alu. Seal Lacq.20mm F/O Top Red Plain
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C / 75% ± 5% RH for 06 months and real time stability study is conducted at 30° C ± 2° C / 75% ± 5% RH for 36 months.

Batches	Mfg date	Batch size
NN7196	May 2017	18160 vials
NN7232	Jun 2017	18160 vials
NN7233	Jun 2017	18160 vials

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	• Submit valid Certificate of Pharmaceutical Product (CoPP) and GMP certificate of the drug product Manufacturer issued by relevant regulatory authority in the country of origin	• The firm submitted that the COPP that we submitted with CTD dossier has a validity till April 2022, as it gets expire during its period in R&I that's why as per the rule it will be considered as valid as we received R&I attested letter on 24th-Februray-2022.
1.3.4	• Submit copy of valid Drug Sale License (DSL) issued by relevant licensing authority	Firm has submitted valid copy of DSL. **DSL No**.: 0230 **Address**: Al Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi **Validity:** 18/05/2024 **Status:** Drug License by way of wholesale
1.3.5	• Submit evidence of approval of manufacturing facility / Approved Section from Licensing Authority	Firm submitted cGMP certificate in name of Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, District Palghar–401506, Mahrashtra State India showing lyophilized / Powder injectable cytotoxic section
1.6.5	• Submit Name and address of API manufacturer.,	• Firm has submitted details of API Manufacturer:

<table>
<tr><td></td><td>• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.</td><td>M/s Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India.
• Firm has submitted cGMP certificate in name of M/s Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India issued by Commissioner Food and Drug Administration Gandhinagar India valid upto 05-09-2025</td></tr>
<tr><td>3.2.S.4</td><td>• Justification is required for selecting different limits of specification of total impurities (Not more than 2.0%) by drug product manufacturer than drug substance manufacturer (Not more than 1.0%)</td><td>• Please note that we are following the BP monograph for analysis of finished product. BP Monograph of Doxorubicin for injection mentions limit of total impurities - Not more than 2.0%. BP monograph of finished product is submitted.</td></tr>
<tr><td>3.2.P.1</td><td>• Justify the role of methyl paraben in the applied formulation
<table>
<tr><th>Applied product</th><th>Reference product</th></tr>
<tr><td>Doxorubicin HCl</td><td>Doxorubicin HCl</td></tr>
<tr><td>Lactose monohydrate</td><td>Lactose Monohydrate</td></tr>
<tr><td>Methyl paraben</td><td></td></tr>
<tr><td>HCl</td><td></td></tr>
<tr><td>NaOH</td><td></td></tr>
<tr><td>Water for injection</td><td></td></tr>
</table>
• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug</td><td>• Methyl paraben is used as Solubilizing agent in the formulation of Doxorubicin for injection 10 mg.
• Methyl paraben occurs as colorless crystals or a white crystalline powder. It is odorless or almost odorless and has a slight burning taste. Methyl paraben is widely used as an antimicrobial preservative in cosmetics, food products, and pharmaceutical formulations. Aqueous solutions at pH 3–6 are stable The WHO has set an estimated total acceptable daily intake for methyl-, ethyl-, and propyl parabens at up to 10 mg/kg body weight and official monograph available in BP.
• However as per Innovator Literature, for Doxorubicin Hydrochloride for Injection particularly used as solubilizing agent which improved or give rapid dissolution of powder in final lyophilized product. Methyl paraben was used in formulation to improve solubilization by reducing the gel formation during reconstitution. Being generic drug of existing Innovator all excipients used as per Innovator and comply as per generic drug definition.
• No information provided</td></tr>
<tr><td>3.2.P.2</td><td>• Submit details of comparator product including name of manufacturer, Batch No#, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted
• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator/comparator product including the tests recommended by BP (Bacterial endotoxin, Water)</td><td>• Information not provided
• Pharmaceutical equivalence was proved on the basis of enclosed comparison of important physicochemical characteristic of innovator product and drug product. Also the proposed Drug product contains same active substance and excipient in similar quantity as that of innovator product. Complete testing as per the any specific pharmacopeia is not necessary during product development as we develop product for global supply with different pharmacopeia. As the results of critical Physicochemical parameters are similar and comparable, therefore both the drug product and innovator product are pharmaceutically equivalent.</td></tr>
</table>

		• Moreover Naprod ensure to perform complete analysis of drug product inline with the BP pharmacopoeia during release of every batch & Submitted stability study.
3.2.P.5.4	• In batch analysis the manufacturing date mentioned on COA of one batch No. NN7233 is Jun 2017 while batch release date is October 2017, clarify the gap between manufacturing date and batch release date.	• Please Note that the batch was manufactured in the end of June 2017. Subsequently the Mother batch was released in July-2017 as per the common pharmacopoeia grades (IP/BP). • Refer enclosed COA of mother batch with common IP/BP pharmacopoeia. Then this batch was charged on the stability study in August 2017. • Later as per export requirement, we have packed and released some quantity from same mother batch as per only BP specification in October-2017. • Since we are proposing the BP grade for finished product in Pakistan registration, we have submitted the same finished product COA which was released as per BP in October-2017 as per Pakistan requirement
3.2.P.8	• Batch release date mentioned in COA of drug product is subsequent to date of initiation of stability study mentioned in stability summary sheets, clarify • The manufacturing date mentioned on COA of batch No. NN7233 is Jun 2017and batch release date is October 2017 while date of initiation of stability study is 24-08-2017, clarify?	• Naprod had manufactured and initially released batch as per common pharmacopoeia (IP/BP) & then charged for stability study to meet domestic as well as export registration requirements. • Later as per Export requirement, we have released some quantity from these batches to export market as per BP pharmacopoeia grade. Since we are proposing the BP grade for finished product in Pakistan registration, we have submitted the same finished product COA which were released subsequently. • Hence COA of these batches have subsequent release date, after stability initiation date.

Remarks of Evaluator: Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Previous Decision (M-324-DRB): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Response of the Firm:

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK **B** SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.

Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt Ltd beside the below mentioned products.

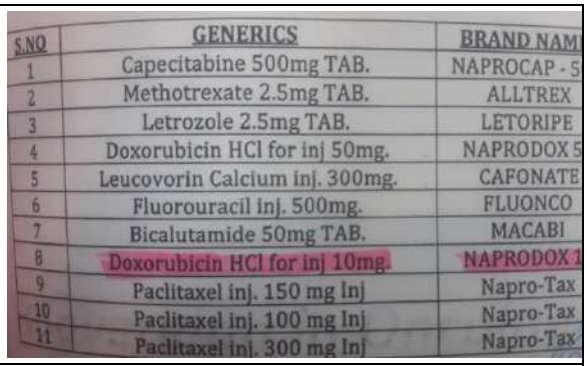
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
8.	Capecitabine 500mg TAB	NAPROCAP -500
9.	Methotrexate 2.5mg TAB	ALLTREX
10.	Doxorubicin HCl for inj 50mg	NAPRODOX 50

11.	Leucovorin Calcium inj. 300mg	CAFONATE
12.	Fluorouracil inj. 500mg	FLUONCO
13.	Bicalutamide 50mg TAB	MACABI
14.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Decision: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email".

816.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot #81, block B, S.M.C.H.S., Karachi.
	Details of Drug Sale License of importer	**DSL No**.: 1245 **Address**: Al-Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** 1. Plot No. 10 Sector 25 KIA Karachi 2. HT-8, Landhi Industrial Area, Karachi **Validity:** 18/05/2022 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Thane–401506, Mahrashtra State India.
	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd., G-17/1, M.I.D.C. Tarapur, Boisar, Distt – Thane – 401506 India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COPP/CERT/KD/104901/2021/11/37012/179916 dated 16/08/2021 issued by Food and Drug Administration Mahrashtra State Mumbai India for Fluonco (Fluorouracil Injection BP 50mg (5ml, 10ml). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The CoPP is valid upto 03/04/2022. The name of importing country mentioned on annexure attached with CoPP is mentioned as Pakistan. **GMP:** Firm has submitted notarized copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 dated 04/04/2019 issued by Food and Drug Administration Mahrashtra Estate Mumbai India The GMP certificate is valid upto 03/04/2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of letter of authorization from M/s Naprod Life Sciences Pvt. Ltd 304, Town Centre-1, Andheri Kurla Road, Andheri (East), Mumbai, India., The letter species that the manufacturer authorizes M/s Al Habib Pharmaceuticals, Plot #81, block B, SMCHS., 74400 Karachi., Pakistan as sole agent and distributor of following drugs only.

		
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5225: dated; 24-02-2022
	Details of fee submitted	PKR 150,000 ; Dated: 26-01-2022 (Deposit slip#24358311719)
	The proposed proprietary name / brand name	**Fluonco injection BP 500mg/10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Fluorouracil injection BP……. 500mg/10ml
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antimetabolites; Pyrimidine analogues WHO ATC Code: L01BC
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fluorouracil 500mg/10ml (50mg/ml) Injection by Accord Healthcare USFDA Approved
	For generic drugs (me-too status)	Flurosol Injection 500mg/10ml by M/s Pharmasol (Pvt) Ltd (Reg. No# 107202)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Nantong Jinghua Pharmaceutical Co., Ltd., No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated study is conducted at 40±2°C/75± 5%RH for 6 months and the real time stability study is conducted at 25 ± 2°C/ 60 ± 5 % RH till 48 months. (Batches: FLU2012001-RD, FLU2012002-RD, FLU2012003-RD)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product Fluorouracil Injection 50mg/ml by M/s Accord Pharmaceutical Ltd., by performing quality tests (Description, pH, Assay, particulate matter, bacterial endotoxin, test for urea, test for related substances).
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, precision, linearity and range, accuracy for the applied product.
	Container closure system of the drug product	10ml 20mm Amber coloured Type-I vial with 20mm Grey Bromo Butyl Rubber stopper with aluminium seal
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C / 75% ± 5% RH for 06 months and real time stability study is

		conducted at 30° C ± 2° C / 75% ± 5% RH for 36 months. **Batches** / **Mfg date** / **Batch size** NN9308-B inverted…LT — Jul 2019 — 22828 vials NN9358-A upright….LT — Aug 2019 — 22828 vials NN9359-A inverted…..LT — Aug 2019 — 22828 vials Firm submitted accelerated stability study data at both orientation (inverted, upright)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	• Submit valid Certificate of Pharmaceutical Product (CoPP) and GMP certificate of the drug product Manufacturer issued by relevant regulatory authority in the country of origin	• The firm submitted that the COPP that we submitted with CTD dossier has a validity till April 2022, as it gets expire during its period in R&I that's why as per the rule it will be considered as valid as we received R&I attested letter on 24th-Februray-2022. • Firm has submitted cGMP certificate of M/s Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Dist. Palghar–401506, Mahrashtra State India issued by Comissioner Food and Drug Administration Maharashtra state India valid upto 27-04-2025
1.3.4	• Submit copy of valid Drug Sale License (DSL) issued by relevant licensing authority	• Firm has submitted valid copy of DSL. **DSL No**.: 0230 **Address**: Al Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi **Validity:** 18/05/2024 **Status:** Drug License by way of wholesale
1.3.5	• Submit evidence of approval of manufacturing facility / Approved Section from Licensing Authority	Firm submitted cGMP certificate in name of Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, District Palghar–401506, Mahrashtra State India showing lyophilized / Powder injectable cytotoxic section
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned as per reference formulation along with submission of applicable fee	Fluorouracil injection BP 500mg/10ml (50mg/ml)
1.6.5	• Submit Name and address of API manufacturer.,	Nantong Jinghua Pharmaceutical Co., Ltd., No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.
3.2.P.1	• Justify the role of Tris Buffer (tromethamine) in the applied formulation **Applied product** / **Reference product** Fluorouracil / Fluorouracil Sodium Hydroxide / Sodium Hydroxide	Based on information and rationale; Tris Buffer used as buffering agent and Sodium Hydroxide as pH adjustifier along with Water for Injection. Selected excipients are very conventional and normally used in Injection manufacturing for their particular function like buffering agent and pH adjuster.

	Tris Buffer (tromethamine) | Water for injection Water for injection |	
3.2.P.2	• Submit details of comparator product including name, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted	• The firm submitted details of reference / comparator product. The details of reference product are: Name: Fluorouracil Injection 50mg/ml; B. No: N03889, Mfg Date: 16-06-2015, Expiry Date: 15-06-2017 Manufacturer by: Accord Pharmaceutical Ltd.
3.2.P.8	• Clarification is required as submitted long term stability summery sheets of drug product conclude as: the product meets the prescribed standards of quality after completion of 18 months long term stability study as per stability indicating specifications, while stability study data upto 36 months is submitted. • The submitted long term stability summary sheets include both the conditions 40° C ± 2° C / 75% ± 5% RH and 30° C ± 2° C / 75% ± 5%, clarify?	• The firm submitted that 36 months stability data submitted but the proposed shelf life mentioned in Stability summary sheet is 24 months. (Stability summary sheet attached) • In the sheet three conditions and temperature are mentioned but the long term and only 30°C ± 2°C and 75% ± 5%RH is marked (✓) which clearly shows the long term stability conducted on 30°C ± 2°C and 75% ± 5%RH (Sheet attach for clarification)

Remarks of Evaluator: Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Previous Decision (M-324th-DRB): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Response of the Firm:

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK **B** SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.

Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt Ltd beside the below mentioned products.

We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
1.	Capecitabine 500mg TAB	NAPROCAP -500
2.	Methotrexate 2.5mg TAB	ALLTREX
3.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
4.	Leucovorin Calcium inj. 300mg	CAFONATE
5.	Fluorouracil inj. 500mg	FLUONCO
6.	Bicalutamide 50mg TAB	MACABI
7.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Decision: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email".

Case No. 14; Deferred Registration Application of Human Drugs on form 5F (cases of Dr. Akbar Ali): Priority applications as per 257th meeting of RB

817.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan, Pakistan
	Details of Drug Sale License of importer	License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	Bioprofarma Bagó S.A. Terrada 1270 - Autonomous City of Buenos Aires, Argentine Republic.
	Name, address of manufacturer(s)	Laboratorio Kemex S.A. Nazarre 3446/54 - Autonomous City of Buenos Aires, Argentine Republic.
	Name of exporting country	Argentine Republic
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. IF-2022-09064835-APN-DFYGR#ANMAT) dated 04-01-2022 issued by National Institute of Drugs Avenida Caseros 2161 Ciudad Autonoma de Buenos Aires-Republica Argentina for Fulvestrant injection 250mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Bioprofarma Bagó S.A. The letter species that the manufacturer appoints M/s BF Biosciences Ltd. to register their products in Pakistan. The authorization letter is valid till 31-01-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.31009 dated No 01-11-2022
	Details of fee submitted	PKR 75,000/-:slip No. 04893286804 dated 25-04-2022
	The proposed proprietary name / brand name	**DIMERE injection 250mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Fulvestrant …….….250mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	oestrogen receptor antagonists (L02BA03)
	Reference to Finished product specifications	In house
	Proposed Pack size	2's
	Proposed unit price	Rs 45,000 /- single dose vial
	The status in reference regulatory authorities	FASLODEX 250mg Injection (AstraZeneca UK Limited). (Pre Filled Syringe of 5 ml)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) – Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 5oC ± 3oC. The stability study data is till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP type-I glass

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25 °C ± 2ºC/ 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5 °C ± 3ºC. The real time stability study data of 3 batches is for 24 months

Evaluation by PEC:

Sr. No	Observations
01	DSL of Importer /applicant is expired till 29-06-2022.
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.

Previous Decision (M-324DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of firm:

Sr#	**Observations**	**Response of Firm**
01	DSL of Importer /applicant is expired till 29-06-2022.	Firm has submitted valid copy of DSL. Details of DSL are; License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.	Firm has submitted valid copy of GMP certificate of API/Drug substance manufacturer, i.e. M/s Farmabios S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 2020-06-12 was valid for three years from date of inspection.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.	Dimere 250mg solution for injection is a generic drug product whose formulation, strength, pharmaceutical form and dosage form are the same as innovator product Falsodex 250mg (Lab. Astra Zeneca) Dimere container closure system differs from Faslodex finished product which is a pre-filled syringe. It consists of vials appropriately closed with stoppers and flip-off aluminium seals evidencing the same quality on materials as pre-filled syringe. Stability studies performed on Dimere dosage form confirms compatibility and that the finished product keeps the original attributes without alteration. Selecting the right primary container presentation for a product is important decision. Dimere is packed in glass vials despite pre-filled syringes advantages due to cost / benefit analysis and

		unavailability to access to required technology facilities to use that container.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.	The firm submitted explanation as: 0.4ml (0.8%) in excess is added per vial during the filling process to ensure the deliverable volume and administration of the labelled doses. The final volume overage was empirically decided during pilot batches evaluation and compliance is confirmed batch to batch by analysis extractable volume

Previous Decision (M-326-DRB): Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting in glass vial

Firm's Response:

The firm has submitted following response;

- Whereas, FULL V (Fulvestrant) 250mg Injection in Vial Form (M/s Laboratorios IMA S.A.I.C, Argentina) is approved for another applicant/importer during 316th (15-18 March 2023) with decision i.e. Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility. **(**Copy of minutes attached). *However, registration letter has not been issued.*
- Additionally, Fulvestrant 250mg/5ml in Vial Form is also suggested to add in WHO Model List of Essential Medicines, WHO Official link and document is attached for your kind reference.
    - *https://www.who.int/news/item/01-10-2021-who-prioritizes-access-to-diabetes-and-cancer-treatments-in-new-essential-medicines-lists*
    - *Application to add Fulvestrant to WHO Model List of Essential Medicines*

In view of above facts and references, we kindly request to re-visit the decision and allow fair chance to BF Biosciences Limited for registration of imported finished drug in Vial form, as BF Biosciences Limited is the joint venture of Ferozsons Laboratories Limited and Bago Laboratories Argentina, and through this joint venture, a number of lifesaving drugs are already registered by DRAP (eg. Panataxel, Donataxel and Oxaltie).

We also would like to apply for exemption of manufacturer abroad as **ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) Argentina is the member of PIC/s.**

Previous Decision (M-330-DRB): Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies, which were adopted by the Registration Board in its 275th meeting in glass vial.

Firm's Response:

- We hereby submitting comprehensive comparison between Innovator and Dimere (Generic) along with relevant reference for your kind consideration and perusal.

Comprehensive Comparison between DIMERE (Generic) and Faslodex (Reference/Innovator)

Feature/Aspect	DIMERE	Faslodex
Active Substance	Fulvestrant 250mg	Fulvestrant 250mg
Formulation Development	Fulvestrant (Anti-estrogen….250mg in 5ml solution for Injection Ethanol (96%, 500 mg) Benzyl alcohol (500 mg) Benzyl benzoate (750 mg) Castor oil q.s to Solvent in IM injection (5ml)	250 mg fulvestrant in 5 ml solution Ethanol (96%, 500 mg) Benzyl alcohol (500 mg) Benzyl benzoate (750 mg) Castor oil refined Qs
Contents of the pack	DIMERE has 2 vials containing Fulvestrant	Faslodex has 2 pack presentations, either a pack containing 1 glass pre-filled syringe containing fulvestrant or a pack containing 2 glass pre-

		filled syringes containing fulvestrant.
Appearance of Drug Product	Solution for Injection Clear, yellowish, viscous liquid, free from particulate matter.	Solution for injection. Clear, colourless to yellow, viscous solution
Pharmaceutical form/Dosage form	Solution for Injection	Solution for Injection
Route of Administration	Intramuscular	Intramuscular
Dosage, Strength/Composition	250mg/5ml, Fulvestrant	250mg/5ml, Fulvestrant
Container-Closure System	Solution for Injection (Vial) (USP Type I Glass Vial;20mm)	Solution for Injection in Pre-filled Syringe (USP-Type-I) SmPC of Faslodex attached
Nature & Contents of Container	Two USP Type I Glass vials appropriately closed with halobutyl stoppers and flip-off aluminium seals.	Two clear type I glass pre-filled syringes with polystyrene plunger rod, fitted with a tamper-evident closure, each containing 5 ml Faslodex solution for injection. Safety needles (BD SafetyGlide) for connection to each barrel are also provided
Manufacturer	Bioprofarma Bagó S.A.	Astra Zeneca
Storage conditions	Refrigerate. It should be stored at 2-8 °C (36-46°F). To protect it from sunlight.	Refrigerate. It should be stored at 2-8 °C (36-46°F). To protect it from sunlight.
Pack Size	2 Vials per Pack	2 PFS per Pack
Shelf Life	2 Years (24 Months)	4 Years
Additional Documents/Studies		
Stability Studies	Fulvestrant 250mg/5ml vial appropriately closed with halobutyl stoppers and flip-off aluminium seals. Stability studies performed on DIMERE confirms compatibility and that finished product keeps the original attributes without alteration. Stability studies are performed justifying the same quality on materials as that of Faslodex in PFS (Stability studies are attached)	
Equivalence Studies	Dimere® 250 mg solution for injection is a Generic Drug Product whose formulation, strength, pharmaceutical form and dosage form are the same as that of the reference medicinal product, Nilgaban® 250 mg (Lab. Tuteur) and innovator product Faslodex® 250 mg (Lab. Astra Zeneca). Equivalence Studies has been studies performed between DIMERE & Nilgaban. (Formulation Development Attached)	
Explanation Letter	Explanation letter of applied container-closure system of finished product is attached Dimere 250mg solution for injection is a generic drug product whose formulation, strength, pharmaceutical form and dosage form are the same as innovator product Falsodex 250mg (Lab. Astra Zeneca) Dimere container closure system differs from Faslodex finished product which is a pre-filled syringe. It consists of vials appropriately closed with stoppers and flip-off aluminium seals evidencing the same quality on materials as pre-filled syringe. Stability studies performed on Dimere dosage form confirms compatibility and that the finished product keeps the original attributes without alteration. Selecting the right primary container presentation for a product is important decision. Dimere is packed in glass vials despite pre-filled syringes advantages due to cost / benefit analysis and unavailability to access to required technology facilities to use that container.	

Addition of Fulvestrant 250mg/5ml vial in WHO Essential Medicine List	• Additionally, Fulvestrant 250mg/5ml in Vial Form is also suggested to add in WHO Model List of Essential Medicines, WHO Official link and document is attached for your kind reference. • *https://www.who.int/news/item/01-10-2021-who-prioritizes-access-to-diabetes-and-cancer-treatments-in-new-essential-medicines-lists* • Application to add Fulvestrant to WHO Model List of Essential Medicines *However, WHO official link states "Other cancer medicines were not recommended for listing due to uncertain additional clinical benefit compared with already listed medicines, high price, and management issues in low-resource settings. These included osimertinib for lung cancer, daratumumab for multiple myeloma, and three types of treatment (CDK4/6 inhibitors, fulvestrant and pertuzumab) for breast cancer.*

• Moreover, the firm submitted that we came to know from market that the similar imported generic product of Fulvestrant 250 mg in Vial form (From Argentina) was approved by DRAP and issued registration letter to that applicant as well. Therefore, we are requesting to kindly re-consider our case for approval on similar grounds and give us a fair chance for registration of this imported product for redressal of needy patients.

Decision: Approved with innovatotr's specifications and as per Policy for inspection of Manufacturer abroad.

- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Original and valid CoPP to I&V section**
  - **ii. Original, notarized, valid letter of authorization**

Case No. 15: Deferred registration applications of Human Drugs on Form 5

818.	Name and Address of Manufacturer / Applicant	Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Metasone Lotion 0.1%.
	Diary No. Date of R&I & fee	***(Duplicate Dossier)*** dated 18/10/2010 Rs. 8000/- (Photocopy fee challan) Differential fee (photocopy) Rs. 12000/- submitted on 26/03/2015 Receipt of application has verified from R&I
	Composition	Each mL contains: Mometasone Furoate…….1mg.
	Pharmacological group	Corticosteroids.
	Type of Form	Form-5
	Finished Product specification	Manufacturer's Specification.
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MOMETASONE-ZP mometasone furoate 0.1% (1MG/GM) w/w lotion bottle by M/s Medis Pharma Pty Ltd, TGA Australia Approved.
	Me-too Status	Hivate (O.1%w/w)of M/s Saffron, Pakistan.
	GMP Status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	Firm applied for 0.1% (1mg/ml) with USP specification. Availability in RRA of 0.1%(1MG/ML) Mometasone Furoate was not confirmed.
	Previouse Decision (M-308th-DRB)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.
	Response of the firm	• Firm has submitted evidence of RRA. Elocon 0.1% w/w Scalp Lotion MHRA Approved

		• Firm has also revised label claim without submission of applicable fee. The revised label claim is as under: Each gram contains: Mometasone Furoate…….1mg
	Decision: Approved with innovator's specifications and following label claim: **Each gram contains:** **Mometasone Furoate…….1mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration Board further decided that registration letter will be issued after submission of following:** **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of strength of the applied formulation) and product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
819.	Name and Address of Manufacturer / Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Ariper Tablet 10mg
	Diary No. Date of R&I & fee	Each tablet contains: Aripiprazole……15mg
	Composition	Dy. No. 13805 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900298 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological group	N05AX12 Other antipsychotics
	Type of Form	Form-5
	Finished Product specification	**USP Specifications**
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Aripiprazole 5, 10, 15 and 30 mg tablets (aripiprazole) - PL 24837/0050-0053; UK/H/5676/001-004/DC MHRA Approved.
	Me-too Status	Mactril tablet 15mg Reg. No. 067735 M/s Wilshire Laboratories Lahore.
	GMP Status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Correction of strength is required along with fee of Rs. 30000/- as brand name indicates 10mg while composition indicates 15mg strength.
	Previouse Decision (M-327th-DRB)	Deferred for following; • Latest GMP inspection report conducted within last three years. • Clarification of applied strength and label.
	Response of the firm	• Firm has submitted cGMP certificate of M/s Panacea Pharmaceuticals issued on 28-04-2023 based on inspection conducted on 24-11-2022. • Firm submitted that we applied for ariper 10mg tablet but in composition mistakenly (typographic mistake) it was written that"Each tablet contains: Aripiprazole….15mg" but in actual we applied for 10mg. Composition should be consider as: Each tablet contains: Aripiprazole…….10mg Me-Too: Apify 10mg Tablet by M/s Akhai Pharmaceuticals (Reg# 76246) Fee for correction of label claim is not submitted
	Decision: Approved with following label claim:	

	Each tablet contains: **Aripiprazole……10mg** • **Registration Board further decided that registration letter will be issued after submission of following:** **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of strength of the applied formulation), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

820.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd.Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 10mg
	Composition	Each Tablet Contains: Methotrexate……..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10798 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants WHO ATC code: L04AX03
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 10mg tablets MHRA Approved
	Me-too-status	Methotrexate tablet 10mg of M/s Pak China International (Reg# 066009)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	The firm revised the 1st page of form 5 as per approved format
	Previous Decision (M-296-DRB)	Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.
	Firm's Response	• The firm submitted that according to W.H.O ATC Classification, our applied product "methotrexate tablet" lie in the category L-04 which refers to IMMUNOSUPPRESSANTS, indicated for the treatment of Rheumatoid Arthritis (ATC Index confirming the same is attached). However, in category L-01, Parenteral formulations used for Neoplastic diseases are classified. • The firm also refer to decision of 271th meeting of registration board, "There is no need for segregated / dedicated / self-contained premises / facilities for the production of drugs belonging to the categories namely immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene. Registration Board decided to grant registration of these products in general manufacturing areas.
	Evaluation by PEC	**Decision of 297th meeting of Registration Board:** Registration Board after thorough deliberation and considering the high-risk classification i.e., "Anticancer (L01)", and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrextare etc.

		in the "Anti-cancer" section only (being high risk products).
	Decision: Deferred for evidence of required manufacturing facility / section of "cytotoxic/oncology tablet section", from Licensing Division since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	
821.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd.Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 2.5mg
	Composition	Each Tablet Contains: Methotrexate……..….2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10797 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 2.5mg Tablets MHRA Approved
	Me-too-status	Methotrexate 2.5mg by PAK CHINA INTERNATIONAL (Reg #066007)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	The firm revised the 1st page of form 5 as per approved format
	Previous Decision (M-296-DRB)	Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.
	Firm's Response	• The firm submitted that according to W.H.O ATC Classification, our applied product "methotrexate tablet" lie in the category L-04 which refers to IMMUNOSUPPRESSANTS, indicated for the treatment of Rheumatoid Arthritis (ATC Index confirming the same is attached). However, in category L-01, Parenteral formulations used for Neoplastic diseases are classified. • The firm also refer to decision of 271th meeting of registration board, "There is no need for segregated / dedicated / self-contained premises / facilities for the production of drugs belonging to the categories namely immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene. Registration Board decided to grant registration of these products in general manufacturing areas.
	Evaluation by PEC	**Decision of 297th meeting of Registration Board:** Registration Board after thorough deliberation and considering the high-risk classification i.e., "Anticancer (L01)", and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrextare etc. in the "Anti-cancer" section only (being high risk products).
	Decision: Deferred for evidence of required manufacturing facility / section of "cytotoxic/oncology tablet section", from Licensing Division since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	

Agenda of Evaluator PEC-XIII.

Case 01: Registration applications Locally manufactured (Human) drugs Routine cases on Form 5F.

822.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 45/2021-DRAP (K) dated 29-09-2021 on the basis of inspection conducted on 27-09-2021 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/98-Lic(Pt-1) dated 07-06-2022 mentioning Eye/Ear drops (Steroid).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28656, dated 10/10/2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 328852081548 dated: 20/09/2022.
	The proposed proprietary name / brand name	Cerucil D Ear Drops.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin as HCl ……3mg Dexamethasone ……. 1mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic/Corticosteroids.
	Pharmaceutical form of applied drug	Ear drops.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1 x 5ml.
	Proposed unit price	238/-
	The status in reference regulatory authorities	CIPRODEX® (ciprofloxacin and dexamethasone), Otic suspension, USFDA approved.
	For generic drugs (me-too status)	Cipotic-D Ear Drops 3m/ml + 1mg/ml, Barrett Hodgson, Reg. No. 032484.
	Name and address of API manufacturer.	**Ciprofloxacin HCl:** Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China. **Dexamethasone:** Zhejiang Xianju Pharmaceutical Co. Ltd. No. 1 Xianyao Road, Xianju Zhejiang China.
	Module-II (Quality Overall	Firm has submitted QOS as per WHO QOS-PD template.

	Summary)	Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Ciprofloxacin HCl:** Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (DK15-2111042a, Mfg. date 11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dexamethasone:** Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (X5-180902, Mfg. date 27-09-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: **Ciprofloxacin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 0701192, 0701193 & 0701194. **Dexamethasone:** Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 150816, 150817 & 150818.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence studies of their product against Cipotec by performing identification, pH, fill volume and drug release. However, drug release has mentioned limit of 75% - 133% and no details of the comparator product are submitted.
	Analytical method validation/verification of product	Not submitted.
STABILITY STUDY DATA		

Manufacturer of API	Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Plastic bottle with cap and nozzle packed in carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 35% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months. Accelerated: 06 months.		
Frequency	Real Time: 0,3,6, 9, 12, 18 & 24 (Months) Accelerated: 0, 03 & 06 (Months).		
Batch No.	TB-101	TB-102	TB-103
Batch Size			
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	
2.	2.3	• Copies of executed BMR's shall be submitted.	
3.	3.2.S.2 & 3.2.S.3	Detailed information of these sections for both the drug substances shall be submitted.	

4.	3.2.S.4.1	Specifications of both the drug substance from both drug substance and drug product manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of both the drug substance from both drug substance and drug product manufacturer shall be submitted.	
6.	3.2.S.4.3	• Analytical method verification of both the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.4.4	• COA of both the drug substances from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of both the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug substance manufacturer as it has mentioned mfg. date of 04-11-2021 while trial batches are manufactured in May, 2019.	
8.	3.2.S.5	Details and COA of the working standard for both the drug substances used shall be submitted.	
9.	3.2.P.1	• Qualitative composition is completely different from the innovator product. Justification shall be submitted. • Innovator product has used benzalkonium chloride as preservative while the applied formulation has no preservative. Clarification shall be submitted.	
10.	3.2.P.2.2	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	
11.	3.2.P.3.5	Process validation protocol shall be submitted.	
12.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.	
13.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justification shall be submitted regarding the submitted chromatograms as they have not shown any wavelength, time, injection volume etc. • Justification shall be submitted regarding the submitted chromatograms for dexamethasone as they are for Opth-Dex eye drops instead for the applied formulation. • Justify the concentration of Dexamethasone i.e. (52.6/1000 = 0.052) with respect to that mentioned in analytical procedure 0.1mg/ml. • Justification shall be submitted for using UV method for the analysis of ciprofloxacin in the assay test in stability studies. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
823.	Name, address of Applicant / Marketing Authorization Holder	**M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.**	
	Name, address of Manufacturing site.	M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	GMP status of the firm	Not submitted.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2013-Lic dated 25-06-2019 specifying Ointment (General) section.	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 28938 dated 12-10-2022.	
	Details of fee submitted	PKR 30,000/- vide slip No. 1738440432 dated: 18/05/2022.	
	The proposed proprietary name / brand name	**Eflor-In Cream 15gm.**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1.5.2: Strength = Eflornithine Hydrochloride 15gm. 3.2.P.1 Eflornithine as Hydrochloride monohydrate ….. 11.9% w/w	
	Pharmacotherapeutic Group of (API)	Not submitted.	
	Pharmaceutical form of applied drug	Topical cream.	
	Reference to Finished product specifications	Manufacturer specification.	
	Proposed Pack size	1 x 15gm.	
	Proposed unit price	As per SRO.	
	The status in reference regulatory authorities	Vaniqa 11.5% cream, MHRA approved. Each gram of cream contains 115 mg of Eflornithine (as hydrochloride monohydrate).	
	For generic drugs (me-too status)	Trichonil 11.5% Cream, Maxitech Pharma, Reg. No. 095186.	
	Name and address of API manufacturer.	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) India.	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and	

		controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. LDX180026, Mfg. date 05-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (LDX180021, LDX180025 & LDX180026)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the product i.e. Depilus Cream by performing quality tests description, identification, deliverable weight, pH, Assay & microbial limits. However, no details of the manufacturer, batch number etc. are given.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Collapsible printed Aluminum tube sealed and packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	6667 Tubes	6667 Tubes	6667 Tubes
Manufacturing Date	07/2021	07/2021	07/2021
Date of Initiation	07-2021	07-2021	07-2021

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
2.	1.5.2	Complete label claim shall be submitted with applicable fee.	
3.		Pharmacotherapeutic group for the applied formulation shall be submitted.	
4.	1.5.8	Evidence of approval of me too product with name of the manufacturer and registration number against the label claim in 1.5.2 and 3.2.P.1 shall be submitted.	
5.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities against the label claim in 1.5.2 and 3.2.P.1 shall be submitted.	
6.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
7.	2.3	• Copies of executed BMR's shall be submitted. • Information submitted by the drug substance manufacturer regarding the drug substance has mentioned BP/Ph. Eur. While the official monograph is not available in these. Clarification shall be submitted.	
8.	3.2.S.2 & 3.2.S.3	Detailed information of these sections for both the drug substances shall be submitted.	
9.	3.2.S.4.1	Specifications of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	
10.	3.2.S.4.2	Analytical procedures of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	

11.	3.2.S.4.4	• Clear and readable copy of COA of the drug substance from drug substance manufacturer shall be submitted. • COAs of the drug substance from both drug substance manufacturer and drug product manufacturer with same batch number shall be submitted.	
12.	3.2.S.4.5	Readable copy of Justification of specification shall be submitted.	
13.	3.2.S.6	Readable copy of container closure system for the drug substance shall be submitted	
14.	3.2.S.7.3	Justification shall be submitted regarding the submission of same stability batches and data of the drug substance as that of linezolid.	
15.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	
16.	3.2.P.2.2	• Justification shall be submitted for not performing PE against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE is performed shall be submitted. • Specifications in the PE studies have mentioned JP specifications. Clarification shall be submitted.	
17.	3.2.P.5.2	• Analytical procedure has mentioned Terbinafine chloride in the assay test. Clarification shall be submitted. • Chromatographic conditions are not mentioned in the analytical procedures. Justification shall be submitted.	
18.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of APLI lot number, initiation date etc. shall be submitted. • Justification shall be submitted for not performing pH and microbial studies of the finished as required by the Specifications of the finished product. • Submitted chromatograms have a run time of 8 minutes while acquisition time is less than 8 minutes. Clarification shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

824.	Name, address of Applicant / Marketing Authorization Holder	**M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2013-Lic dated 13/07/2017 specifying Tablet (General) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29839 dated 21-10-2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 5363423303 dated: 14/04/2022.
	The proposed proprietary name / brand name	**Ledenzo-Lid 600mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……. …… 600mg
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1 x 10's.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	ZYVOX® (linezolid) 600mg tablets, USFDA approved.
	For generic drugs (me-too status)	Lyzon 600mg Tablet, Getz Pharma, Reg. No. 055439.
	Name and address of API manufacturer.	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. LDX180026, Mfg. date 05-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (LDX180021, LDX180025 & LDX180026)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical

		development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product i.e. Zolrest 600mg tablets, by performing quality tests average weight, Dissolution & Assay. Results of both the test product and comparator product are comparable. Comparative Dissolution is also performed against the same product i.e. Zolrest 600mg tablets, B. No. 210582, Exp. date 03-2023 manufactured by M/s Bosch Pharmaceuticals. *However, only details of the product is submitted while no data for CDP studies is submitted by the firm.*
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu/Alu Blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	07/2021	07/2021	07/2021
Date of Initiation	07-2021	07-2021	07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
14.	1.3.4	• Valid copy of DML of the applicant shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
15.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
16.	2.3	Copies of executed BMR's shall be submitted.	
17.	3.2.S.2 & 3.2.S.3	Detailed information of these sections for both the drug substances shall be submitted.	
18.	3.2.S.4.1	Specifications of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	
19.	3.2.S.4.2	Analytical procedures of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted	
20.	3.2.S.4.4	• Clear and readable copy of COA of the drug substance from drug substance manufacturer shall be submitted. • COAs of the drug substance from both drug substance manufacturer and drug product manufacturer with same batch number shall be submitted.	
21.	3.2.S.4.5	Readable copy of Justification of specification shall be submitted.	
22.	3.2.S.6	Readable copy of container closure system for the drug substance shall be submitted	
23.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	
24.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE is performed shall be submitted. • Results of the CDP studies in all the three mediums with calculation of F_2 value shall be submitted.	
25.	3.2.P.5.1	This section has mentioned In-House specification. Justification shall be submitted.	
26.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of APLI lot number, initiation date etc. shall be submitted. • Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph. • Justification shall be submitted regarding the initial time results of dissolution test as they are out of specification.	

		• Justification shall be submitted regarding the concentration of standard solution in raw data sheets (0.049 mg/ml) as it is different from that given in the formula (0.06mg/ml). • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

825.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted inspection report dated 20-02-2019. Not valid.
	Evidence of approval of manufacturing facility	Firm has submitted approval of layout plan instead of section approval letter.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29325 dated 17-10-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 8013542500 Dated 28/09/2022.
	The proposed proprietary name / brand name	**Salefo 5mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin succinate ……. 5mg
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence (G04BD)
	Pharmaceutical form of applied drug	Oral tablet.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	VESICARE (solifenacin succinate) 5mg & 10mg tablets, USFDA approved.
	For generic drugs (me-too status)	Solifen Tablets 5mg, Getz Pharma, Registration No. 061202.

	Name and address of API manufacturer.	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (15001825003, mfg. date 26-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 15001328001, 15001329003, 15001429001.
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the comparator product i.e. Solifen 5mg tablets, B. No. 090F52, mfg. date 10-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, Average weight & Comparative Dissolution). CDP has been performed against the same brand in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both the applied formulation and comparator product has more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA	
Manufacturer of API	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.
API Lot No.	15001825003.
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Tablets.	1200 Tablets.	1200 Tablets.
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	05-03-2022	05-03-2022	05-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NCF-II/1827/001/CAT dated 13-07-2018 issued by Ministry of Health of Government of Catalonia – Spain issued on the basis of inspection conducted on 25, 26, 27 & 28 July, 2016 valid for a period three years from the date of inspection is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. 00148/2022-DRAP(P)/394 dated 28-01-2022 mentioning Solifenacin Succinate EP attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm.
1.	1.3.4	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 27-09-2013. Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.2	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.	

4.	1.5.5	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.	
5.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	
6.	2.3	Table for literature references with correct information regarding the drug substance shall be submitted.	
7.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.	
8.	3.2.S.4.2	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted. • Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.	
9.	3.2.S.4.3	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.	
10.	3.2.S.5	• COA and details of the reference/working standard used in the development studies shall be submitted.	
11.	3.2.S.7.3	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.	
12.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.	
13.	3.2.P.5.1	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.	
14.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for assay test on UV method instead of HPLC in the analytical procedures..	
15.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.	
16.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.	
17.	3.2.P.8	• Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test. • Justification shall be submitted regarding the submitted chromatograms as the analytical method has mentioned UV method for the analysis of assay test while the submitted chromatograms are of HPLC. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
826.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.	
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	GMP status of the firm	Firm has submitted inspection report dated 20-02-2019. Not valid.	
	Evidence of approval of manufacturing facility	Firm has submitted approval of layout plan instead of section approval letter.	
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 29841 dated 21-10-2022.	
	Details of fee submitted	PKR 30,000/-, vide slip No. 46716000 Dated 28/09/2022.	
	The proposed proprietary name / brand name	**Salefo 10mg tablets.**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin succinate ……. 10mg	
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence (G04BD)	
	Pharmaceutical form of applied drug	Oral tablet.	
	Reference to Finished product specifications	Innovator's Specifications.	
	Proposed Pack size	As per SRO.	
	Proposed unit price	As per SRO.	
	The status in reference regulatory authorities	VESICARE (solifenacin succinate) 5mg & 10mg tablets, USFDA approved.	
	For generic drugs (me-too status)	Solifen Tablets 10mg, Getz Pharma, Registration No. 061203.	
	Name and address of API manufacturer.	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and	

		justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (15001825003, mfg. date 26-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 15001328001, 15001329003, 15001429001.
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the comparator product i.e. Solifen 10mg tablets, B. No. 100F84, mfg. date 10-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, Average weight & Comparative Dissolution). CDP has been performed against the same brand in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both the applied formulation and comparator product has more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.		
API Lot No.	15001825003.		
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06

Batch Size	1200 Tablets.	1200 Tablets.	1200 Tablets.
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	05-03-2022	05-03-2022	05-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NCF-II/1827/001/CAT dated 13-07-2018 issued by Ministry of Health of Government of Catalonia – Spain issued on the basis of inspection conducted on 25, 26, 27 & 28 July, 2016 valid for a period three years from the date of inspection is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. 00148/2022-DRAP(P)/394 dated 28-01-2022 mentioning Solifenacin Succinate EP attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm.
1.	1.3.4	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 27-09-2013. Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.2	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.	
4.	1.5.5	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.	
5.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	
6.	2.3	Table for literature references with correct information regarding the drug substance shall be submitted.	
7.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.	

8.	3.2.S.4.2	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted. • Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.	
9.	3.2.S.4.3	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.	
10.	3.2.S.5	• COA and details of the reference/working standard used in the development studies shall be submitted.	
11.	3.2.S.7.3	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.	
12.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.	
13.	3.2.P.5.1	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.	
14.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for performing assay test on UV method instead of HPLC.	
15.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.	
16.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.	
17.	3.2.P.8	• Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test. • Justification shall be submitted regarding the submitted chromatograms as the analytical method has mentioned UV method for the analysis of assay test while the submitted chromatograms are of HPLC. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

827.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**

	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 165/2022-DRAP (K) dated 15-09-2022 issued on the basis of inspection conducted on 09-09-2022.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 2-6/86-Lic (Vol-V) dated 13-09-2021 wherein Tablet (General) section of the firm is approved.
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29856 dated 21-10-2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 48654523338 Dated 20-06-2022.
	The proposed proprietary name / brand name	**Amlodipine 5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet contains: Amlodipine Besylate eq. to Amlodipine ……. 5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers.
	Pharmaceutical form of applied drug	Film coated tablets.
	Reference to Finished product specifications	USP Specification.
	Proposed Pack size	30’s.
	Proposed unit price	As per DPC/SRO.
	The status in reference regulatory authorities	Norvasc 2.5mg, 5mg & 10mg Tablet (amlodipine besylate), US FDA Approved.
	For generic drugs (me-too status)	Norvasc 10mg Tablet, Pfizer Pharma, Reg. No. 011825.
	Name and address of API manufacturer.	M/s Amsal Chem Pvt. Ltd., A-1, 401,402 & 403 GIDC, Ankleshwar, Dist. Bharuch, Gujrat State, India. Copy of GMP certificate No. 1991611 dated 24-09-2019 issued by FDA Gujrat State, India valid till 23-09-2022 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted details of the drug substance including its nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 21004/AB, Mfg. date 16-02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 13018/AB, 13019/AB &14001/AB
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Reference product that is Norvasc 5mg Tablet, Batch No: FH5563, Exp. date 05-2024 manufactured by Pfizer Pakistan by performing quality tests i.e. identification, Weight variation, Disintegration time, Dissolution, Impurities & Assay. CDP has been performed against the same brand that is Norvasc 5mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Results have shown more than 85% release within 15 minutes for both the test product and innovator product in all the above mentioned three mediums.
	Analytical method validation/verification of product	Method verification studies have submitted including Accuracy, Precision, Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Amsal Chem Pvt. Ltd., A-1, 401,402 & 403 GIDC, Ankleshwar, Dist. Bharuch, Gujrat State, India.		
API Lot No.	2201000172. (21004/AB as per drug substance manufacturer).		
Description of Pack (Container closure system)	Alu-PVDC blister of 10's packed in printed unit carton, further packed in a master shipper (3 x 10's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1868-S	NPD-T-1875-S	NPD-T-1876-S
Batch Size	1500 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	10-02-2022	15-02-2022	15-02-2022
Date of Initiation	24-02-2022	24-02-2022	24-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021 Inspection was conducted on 04th January, 2020. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 1991611 dated 24-09-2019 issued by FDA Gujrat State, India valid till 23-09-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that their product is not film coated and they have submitted the same in the Cover letter, Form 5F, and Section 3.2.P.1 (master formula).
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant regulatory authority shall be submitted.	Copy of GMP certificate No. 22103633 dated 20-10-2022 issued by FDA Gujrat State, India valid till 19-10-2025 is submitted.
3.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted that at the time of product development, they prospected many suppliers/vendors but could not easily got the drug substance for trial and development purpose. Therefore, the API was procured free of cost from indenter GUDIA PRIVATE LIMITED on their letter head. So, we request the esteemed authority to consider the attached document for processing of our application and approval of the product. However, we hereby commit to follow the invoice clearance from I&E DRAP for imported materials in the future for product development and stability studies.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
828.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 165/2022-DRAP (K) dated 15-09-2022 issued on the basis of inspection conducted on 09-09-2022.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 2-6/86-Lic (Vol-V) dated 13-09-2021 wherein Tablet (General) section of the firm is approved.
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29857 dated 21-10-2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 0219756228 Dated 20-06-2022.
	The proposed proprietary name / brand name	**Amlodipine 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet contains: Amlodipine Besylate eq. to Amlodipine …… 10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers.
	Pharmaceutical form of applied drug	Film coated tablets.
	Reference to Finished product specifications	USP Specification.
	Proposed Pack size	30’s.
	Proposed unit price	As per DPC/SRO.
	The status in reference regulatory authorities	Norvasc 2.5mg, 5mg & 10mg Tablet (amlodipine besylate), US FDA Approved.
	For generic drugs (me-too status)	Norvasc 10mg Tablet, Pfizer Pharma, Reg. No. 011826.
	Name and address of API manufacturer.	M/s Amsal Chem Pvt. Ltd., A-1, 401,402 & 403 GIDC, Ankleshwar, Dist. Bharuch, Gujrat State, India. Copy of GMP certificate No. 1991611 dated 24-09-2019 issued by FDA Gujrat State, India valid till 23-09-2022 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 21004/AB, Mfg. date 16-02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 13018/AB, 13019/AB &14001/AB
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Reference product that is Norvasc 10mg Tablet, Batch No: FF3953, Exp. date 07-2023 manufactured by Pfizer Pakistan by performing quality tests i.e. identification, Weight variation, Disintegration time, Dissolution, Impurities & Assay. CDP has been performed against the same brand that is Norvasc 10mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Results have shown more than 85% release within 15 minutes for both the test product and innovator product in pH 1.2 & 4.5 while the value of F_2 in pH 6.8 is in acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Accuracy, Precision, Specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Amsal Chem Pvt. Ltd., A-1, 401,402 & 403 GIDC, Ankleshwar, Dist. Bharuch, Gujrat State, India.
API Lot No.	2201000172. (21004/AB as per drug substance manufacturer).
Description of Pack (Container closure system)	Alu-PVDC blister of 10's packed in printed unit carton, further packed in a master shipper (3 x 10's).
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	NPD-T-1863-S	NPD-T-1869-S	NPD-T-1870-S
Batch Size	1500 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	09-02-2022	11-02-2022	11-02-2022
Date of Initiation	24-02-2022	24-02-2022	24-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021 Inspection was conducted on 04th January, 2020. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 1991611 dated 24-09-2019 issued by FDA Gujrat State, India valid till 23-09-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that their product is not film coated and they have submitted the same in the Cover letter, Form 5F, and Section 3.2.P.1 (master formula).
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant regulatory authority shall be submitted.	Copy of GMP certificate No. 22103633 dated 20-10-2022 issued by FDA Gujrat State, India valid till 19-10-2025 is submitted.
3.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted that at the time of product development, they prospected many suppliers/vendors but could not easily got the drug substance for trial and development purpose. Therefore, the API was procured free of cost from indenter GUDIA PRIVATE LIMITED on their letter head. So, we request the esteemed authority to consider the attached document for processing of our application and approval of the product.

			However, we hereby commit to follow the invoice clearance from I&E DRAP for imported materials in the future for product development and stability studies.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

829.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan Pharmaceuticals (Pvt.) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceuticals (Pvt.) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 33968 dated 24-11-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 0727272806 dated 28-10-2022.
	The proposed proprietary name / brand name	**Lozar 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…50mg
	Pharmacotherapeutic Group of (API)	Anti hypertensive.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Cozzar 50mg Tablet, M/s OBS Pakistan limited, Reg. No. 022067.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.P.2.2	• Assay specifications has mentioned 94.5% - 105% in this section while USP has mentioned 95% - 105%. Clarification shall be submitted. • CDP studies of the applied formulation with innovator/comparator product shall be submitted.	

5.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	
6.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board shall be submitted with inclusion of API lot number. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

830.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 34294 dated 28-11-2022.
	Details of fee submitted	Rs.75,000/- vide slip No. 7753971259 dated 24-11-2022.
	The proposed proprietary name / brand name	**Bempiglob-E Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Bempedoic acid …… 180mg Ezetimibe ……..…….... 10mg
	Pharmacotherapeutic Group of (API)	Combination of various lipid modifying agents. C10BA10.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	NEXLIZET (Bempedoic acid and ezetimibe) tablets, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's & 30's.
	Proposed unit price	As per Policy.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.5.6	Valid copies of GMP certificate of both the drug substances issued by relevant/concerned regulatory authorities shall be submitted.	Bempedoic acid; Firm has submitted copy of license retention certificate No. HMF07-19024/2022-TECH-DCA issued by Director & Licensing Authority, DCA Andhra Pradesh valid till 07-05-2027. Ezetimibe: Firm has submitted copy of manufacturing license No. Zhe 20050431 valid till 16-06-2025.

2.	3.2.S.4.3	Analytical record/Raw data for verification of the drug substance Bempedoic acid performed by the drug product manufacturer shall be submitted.	Firm has submitted analytical record for the drug substance Bempedoic acid wherein the run time of the sample is as per drug substance manufacturer i.e. 40 minutes.
3.	3.2.S.7.3	Complete real time stability studies for Bempedoic acid as per Zone IV a shall be submitted.	Firm has submitted 24 month real time stability studies of the drug substance.
4.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Clarification/drug excipients compatibility studies shall be submitted.	Firm has submitted that qualitative composition of the applied formulation is same as innovator product i.e. Nexlizet Tablets, USFDA.
5.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

831.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35345 dated 06-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 74692864338 dated 30-11-2022.
	The proposed proprietary name / brand name	**Losartan 25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Losartan Potassium ……..…25mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Losmart Tablet 25mg, M/s Scilife Pharma, Reg. No. 096990.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.5.2	This section has not mentioned film coating while the reference product is film coated tablet. Clarification shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
4.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
6.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	
8.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
9.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
10.	3.2.P.2.2	Justification shall be submitted for not performing CDP & PE studies against the innovator product.	
11.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

832.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35346 dated 06-12-2022.

	Details of fee submitted	Rs.30,000/- vide slip No. 3173706031 dated 30-11-2022.
	The proposed proprietary name / brand name	**Losartan 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…50mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Losmart Tablet 50mg, M/s Scilife Pharma, Reg. No. 096991.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
8.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

833.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35347 dated 06-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 40374714087 dated 30-11-2022.
	The proposed proprietary name / brand name	**Losartan 100mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…100mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	A2A 100mg Tablet, M/s Wilsons Pharma, Reg. No. 059309.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the	

		analytical procedures are completely different from USP. Clarification shall be submitted.	
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
8.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

834.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 36117 dated 12-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 5200767411 dated 27-10-2022.
	The proposed proprietary name / brand name	**Zolapt 40mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Omeprazole EC Pellets …40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Omeprazole 20mg & 40mg capsule (delayed release pellets), USFDA Approved.
	For generic drugs (me-too status)	Risek 40mg capsule, M/s Getz pharma Karachi, Reg. No. 022109.
	Proposed Pack size	10’ & 14’s.
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply submitted by the firm.**
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	

2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.4	• COA submitted by the drug product manufacturer has mentioned dissolution specifications of NMT 15% in 0.1N HCl while drug substance manufacturer has mentioned NMT 10%. Clarification shall be submitted. • Dissolution specification in buffer has mentioned NMT 75% while drug substance manufacturer has mentioned NLT 75%. Clarification shall be submitted.	
5.	3.2.P.2.2	• Details of the comparator product against which PE studies are performed shall be submitted. • Calculation and values of F_2 shall be submitted for each medium.	
6.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	
7.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

835.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37078 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 7425144167 dated 12-12-2022.
	The proposed proprietary name / brand name	**Rosca Plus Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 5mg Ezetimibe …….. 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Alzil plus 5 mg/10 mg film-coated tablets, CIMA Spain approved.
	For generic drugs (me-too status)	Rovista EZ Tablet, Getz pharma, Reg. No. 073716.
	Proposed Pack size	7's, 9's, 10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copies of GMP certificate of both the drug substances issued by concerned/relevant regulatory authorities shall be submitted.	Ezetimibe: Firm has submitted copy of GMP certificate No. MI-2022-CE-08738-1 dated 03-08-2022 in the name of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15 Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw materials base Linhai Zone, Taizhou City issued by TGA Australia valid till 10-09-2025. Rosuvastatin: Firm has submitted a written confirmation for Pharmaceutical product issued by Shaoguan Pharmaceutical Association valid till 11-01-2026. *Not from relevant authority.*
2.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that as per the supplier's and In-house Certificate of Analysis (CoA), In-house method, and the USP monograph, the water content limit is not more than (NMT) 6.0%. However, Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5%.
3.	3.2.S.4.3	• Analytical method verification studies of the drug substance Rosuvastatin calcium performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.1	• According to the formulation development data, the applied product is bilayer film coated tablet, while section 1.5.2 has mentioned only film coated tablet. Clarification shall be submitted. • Reference product of Spain is also a film coated tablet. Clarification shall be submitted.	Firm has submitted that according to literature survey regarding the Rosuvastatin and Ezetimibe, both molecules are not compatible with each other. Keeping an eye over the said issue, the formulation was designed as film coated tablet with bilayer inner core. Rosuvastatin is more stable in near neutral to alkaline pH, the same is detrimental to ezetimibe. Hence it is important to separate the two individual molecules, which creates a significant product development challenge. Hence, we have formulated bilayer core with outer film coating. *Applied strength is only available in Spain while other strengths of the same formulation are available in different RRAs with both film coated and bilayer tablets.*
5.	3.2.P.2.2	Pictorial evidence of the innovator product with visible details of batch number manufacturing date etc. shall be submitted.	Submitted and same details as provided in PE and CDP studies.

6.	3.2.P.5.2	• Justify for using same dissolution medium for both active substances when the innovator brand also recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances. • Justification shall be submitted for using 45 minutes' time for dissolution while the review of innovator brand has mention 30minutes.	Firm has submitted that they have performed the Comparative Dissolution Profile (CDP) of rosuvastatin and ezetimibe tablets with the innovator tablet. By considering solubility characteristics and profiling data with Innovator we select phosphate buffer pH 6.8 with 0.45% SLS as dissolution This medium ensures accurate, reliable, and reproducible results for rosuvastatin and ezetimibe tablets. We conducted the dissolution test for both rosuvastatin and ezetimibe on the combined product at 50 rpm instead of the 75 rpm as well as CDP releasing profile compare with innovator. On the basis of these study we extended our dissolution time up to 45 minutes. *Review of the innovator product recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances while the applied formulation has not followed the same.*
7.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone) Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved.

- **Registration letter will be issued after submission of valid copy of GMP certificate/ Drug manufacturing license of the drug substance (Rosuvastatin) manufacturer i.e. Ruyuan HEC Pharm Co., Ltd. Xaiba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

836.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37079 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 3248881128 dated 12-12-2022.

	The proposed proprietary name / brand name	**Rosca Plus Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium ……. …… 10mg Ezetimibe …….. 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Twicor 10 mg/10 mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Rovista EZ 10/10mg Tablet, Getz pharma, Reg. No. 073718.
	Proposed Pack size	7's, 9's, 10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has mentioned Rosuvastatin 10 mg while the innovator product/reference product has mentioned Rosuvastatin as calcium 10mg. Clarification shall be submitted.	Firm has submitted revised the label claim as per reference product as follows: Each Film Coated Tablet contains: Rosuvastatin Calcium eq.to Rosuvastatin ……..….10mg Ezetimibe ……... 10mg *However, fee for revision of label claim is not submitted.*
2.	1.6.5	Valid copies of GMP certificate of both the drug substances issued by concerned/relevant regulatory authorities shall be submitted.	Ezetimibe: Firm has submitted copy of GMP certificate No. MI-2022-CE-08738-1 dated 03-08-2022 in the name of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15 Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw materials base Linhai Zone, Taizhou City issued by TGA Australia valid till 10-09-2025. Rosuvastatin: Firm has submitted a written confirmation for Pharmaceutical product issued by Shaoguan Pharmaceutical Association valid till 11-01-2026. *Not from relevant authority.*
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that as per the supplier's and In-house Certificate of Analysis (CoA), In-house method, and the USP monograph, the water content limit is not more than (NMT) 6.0%. However, Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5%.
4.	3.2.S.4.3	Analytical method verification studies of both the drug substances	Submitted.

		performed by the drug product manufacturer shall be submitted.	
5.	3.2.P.1	According to the formulation development data, the applied product is bilayer film coated tablet, while section 1.5.2 has mentioned only film coated tablet. Clarification shall be submitted.	Firm has submitted that according to literature survey regarding the Rosuvastatin and Ezetimibe, both molecules are not compatible with each other. Keeping an eye over the said issue, the formulation was designed as film coated tablet with bilayer inner core. Rosuvastatin is more stable in near neutral to alkaline pH, the same is detrimental to ezetimibe. Hence it is important to separate the two individual molecules, which creates a significant product development challenge. Hence, we have formulated bilayer core with outer film coating. *However, firm has not replied regarding the film coating and bilayer tablet in section 1.5.2.*
6.	3.2.P.2.2	Pictorial evidence of the innovator product with visible details of batch number manufacturing date etc. shall be submitted.	Submitted and same details as provided in PE and CDP studies.
7.	3.2.P.5.2	• Justify for using same dissolution medium for both active substances when the innovator brand has recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances. • Justification shall be submitted for using 45 minutes' time for dissolution while the review of innovator brand has mention 30minutes.	Firm has submitted that they have performed the Comparative Dissolution Profile (CDP) of rosuvastatin and ezetimibe tablets with the innovator tablet. By considering solubility characteristics and profiling data with Innovator we select phosphate buffer pH 6.8 with 0.45% SLS as dissolution This medium ensures accurate, reliable, and reproducible results for rosuvastatin and ezetimibe tablets. We conducted the dissolution test for both rosuvastatin and ezetimibe on the combined product at 50 rpm instead of the 75 rpm as well as CDP releasing profile compare with innovator. On the basis of these study we extended our dissolution time up to 45 minutes. *Review of the innovator product recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances while the applied formulation has not followed the same.*
8.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone) Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved with following label claim;
Each Film Coated Tablet contains:
Rosuvastatin Calcium eq.to Rosuvastatin ……10mg
Ezetimibe …….. 10mg

- **Registration letter will be issued after submission of full fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and valid copy of GMP certificate/ Drug manufacturing license of the drug substance (Rosuvastatin) manufacturer i.e. Ruyuan HEC Pharm Co., Ltd. Xaiba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

837.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37080 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 5927499841 dated 12-12-2022.
	The proposed proprietary name / brand name	**Rosca Plus Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin …… 20mg Ezetimibe …….. 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Twicor 20 mg/10 mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Rovista EZ 20/10mg Tablet, Getz pharma, Reg. No. 073717.
	Proposed Pack size	7's, 9's, 10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has mentioned Rosuvastatin 20 mg while the innovator product/reference product has mentioned Rosuvastatin as calcium 20mg. Clarification shall be submitted.	Firm has submitted revised the label claim as per reference product as follows: Each Film Coated Tablet contains: Rosuvastatin Calcium eq.to Rosuvastatin ……..….20mg Ezetimibe …….. 10mg *However, fee for revision of label claim is not submitted.*
2.	1.6.5	Valid copies of GMP certificate of both the drug substances issued by concerned/relevant regulatory authorities shall be submitted.	Ezetimibe: Firm has submitted copy of GMP certificate No. MI-2022-CE-08738-1 dated 03-08-2022 in the name of M/s Zhejiang Tianyu

			Pharmaceutical Co., Ltd., No. 15 Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw materials base Linhai Zone, Taizhou City issued by TGA Australia valid till 10-09-2025. Rosuvastatin: Firm has submitted a written confirmation for Pharmaceutical product issued by Shaoguan Pharmaceutical Association valid till 11-01-2026. *Not from relevant authority.*
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that as per the supplier's and In-house Certificate of Analysis (CoA), In-house method, and the USP monograph, the water content limit is not more than (NMT) 6.0%. However, Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5%.
4.	3.2.S.4.3	Analytical method verification studies of both the drug substances performed by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.1	According to the formulation development data, the applied product is bilayer film coated tablet, while section 1.5.2 has mentioned only film coated tablet. Clarification shall be submitted.	Firm has submitted that according to literature survey regarding the Rosuvastatin and Ezetimibe, both molecules are not compatible with each other. Keeping an eye over the said issue, the formulation was designed as film coated tablet with bilayer inner core. Rosuvastatin is more stable in near neutral to alkaline pH, the same is detrimental to ezetimibe. Hence it is important to separate the two individual molecules, which creates a significant product development challenge. Hence, we have formulated bilayer core with outer film coating. *However, firm has not replied regarding the film coating and bilayer tablet in section 1.5.2.*
6.	3.2.P.2.2	Pictorial evidence of the innovator product with visible details of batch number manufacturing date etc. shall be submitted.	Submitted and same details as provided in PE and CDP studies.
7.	3.2.P.5.2	• Justify for using same dissolution medium for both active substances when the innovator brand has recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances.	Firm has submitted that they have performed the Comparative Dissolution Profile (CDP) of rosuvastatin and ezetimibe tablets with the innovator tablet. By considering solubility characteristics and profiling data with Innovator we select phosphate buffer pH 6.8 with 0.45% SLS as dissolution This medium ensures accurate, reliable, and reproducible results for rosuvastatin and ezetimibe tablets.

		• Justification shall be submitted for using 45 minutes' time for dissolution while the review of innovator brand has mention 30minutes.	We conducted the dissolution test for both rosuvastatin and ezetimibe on the combined product at 50 rpm instead of the 75 rpm as well as CDP releasing profile compare with innovator. On the basis of these study we extended our dissolution time up to 45 minutes. *Review of the innovator product recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances while the applied formulation has not followed the same.*
8.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone) Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved with following label claim;
Each Film Coated Tablet contains:
Rosuvastatin Calcium eq.to Rosuvastatin ……10mg
Ezetimibe …….. 10mg

- **Registration letter will be issued after submission of full fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and valid copy of GMP certificate/ Drug manufacturing license of the drug substance (Rosuvastatin) manufacturer i.e. Ruyuan HEC Pharm Co., Ltd. Xaiba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

838.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37081 dated 20-12-2022.
	Details of fee submitted	Rs.75,000/- vide slip No. 6845263523 dated 12-12-2022.
	The proposed proprietary name / brand name	**Rosca Plus Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 40mg Ezetimibe …….. 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Innovator's Specifications.

	The status in reference regulatory authorities	Zenon 40/10mg film coated tablets, MHRA approved.
	For generic drugs (me-too status)	Not applicable.
	Proposed Pack size	7's, 9's, 10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copies of GMP certificate of both the drug substances issued by concerned/relevant regulatory authorities shall be submitted.	Ezetimibe: Firm has submitted copy of GMP certificate No. MI-2022-CE-08738-1 dated 03-08-2022 in the name of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15 Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw materials base Linhai Zone, Taizhou City issued by TGA Australia valid till 10-09-2025. Rosuvastatin: Firm has submitted a written confirmation for Pharmaceutical product issued by Shaoguan Pharmaceutical Association valid till 11-01-2026. *Not from relevant authority.*
2.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that as per the supplier's and In-house Certificate of Analysis (CoA), In-house method, and the USP monograph, the water content limit is not more than (NMT) 6.0%. However, Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5%.
3.	3.2.S.4.3	Analytical method verification studies of both the drug substances performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.1	According to the formulation development data, the applied product is bilayer film coated tablet, while section 1.5.2 has mentioned only film coated tablet. Clarification shall be submitted.	Firm has submitted that according to literature survey regarding the Rosuvastatin and Ezetimibe, both molecules are not compatible with each other. Keeping an eye over the said issue, the formulation was designed as film coated tablet with bilayer inner core. Rosuvastatin is more stable in near neutral to alkaline pH, the same is detrimental to ezetimibe. Hence it is important to separate the two individual molecules, which creates a significant product development challenge. Hence, we have formulated bilayer core with outer film coating. *However, firm has not replied regarding the film coating and bilayer tablet in section 1.5.2.*

5.	3.2.P.2.2	Pictorial evidence of the innovator product with visible details of batch number manufacturing date etc. shall be submitted.	Submitted and same details as provided in PE and CDP studies.
6.	3.2.P.5.2	• Justify for using same dissolution medium for both active substances when the innovator brand has recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances. • Justification shall be submitted for using 45 minutes' time for dissolution while the review of innovator brand has mention 30minutes.	Firm has submitted that they have performed the Comparative Dissolution Profile (CDP) of rosuvastatin and ezetimibe tablets with the innovator tablet. By considering solubility characteristics and profiling data with Innovator we select phosphate buffer pH 6.8 with 0.45% SLS as dissolution This medium ensures accurate, reliable, and reproducible results for rosuvastatin and ezetimibe tablets. We conducted the dissolution test for both rosuvastatin and ezetimibe on the combined product at 50 rpm instead of the 75 rpm as well as CDP releasing profile compare with innovator. On the basis of these study we extended our dissolution time up to 45 minutes. *Review of the innovator product recommended two different dissolutions medium (pH 6.6 citrate buffer with 50 RPM for rosuvastatin & pH 4.5 acetate buffer with 0.45% SLS and 75 RPM for Ezetimibe) for both active substances while the applied formulation has not followed the same.*
7.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone) Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved. Registration letter will be issued after submission of valid copy of GMP certificate/ Drug manufacturing license of the drug substance (Rosuvastatin) manufacturer i.e. Ruyuan HEC Pharm Co., Ltd. Xaiba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

839.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 969 dated 11-01-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 71393543061 dated 22-09-2022.

	The proposed proprietary name / brand name	**Baclast 0.05mg/ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Baclofen …….. 0.05mg.
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Baclofen 0.05 mg/1 ml solution for injection, MHRA approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	1 ampoule, 5 ampoule & 10ml ampoule.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
	1.5.7	This section has mentioned oral route of administration. Clarification shall be submitted.	Firm has submitted that it is a typographical error. Baclast Injection 0.05mg/ml is Intrathecal Injection.
8.	1.5.9	Evidence of approval of applied formulation in applied fill volume (2ml) in RRAs shall be submitted.	Firm has submitted that Innovator **Lioresal Intrathecal injection** is using 1ml Ampule for filling 0.05mg/ml. The developed product was filled in 2ml ampule due to shortage of 1ml Ampule to conduct the stability studies maintaining the label claim of 0.05mg/ml.
9.	3.2.S.7.3	Stability data sheets have mentioned Assay test by HPLC while the analytical procedures have mentioned potentiometric method. Clarification shall be submitted.	Firm has submitted that drug substance manufacturer M/s Panchsheel Organics Limited stated that "There was a typographical error in the ODMF. Mistakenly the Assay was mentioned as "By HPLC" instead of "By Potentiometric Titration". They also submitted revised stability studies with Potentiometric Titration
10.	3.2.P.2.2	Pictorial evidence of the innovator product against which PE studies are performed shall be submitted with clear details of batch number, manufacturing date and manufacturer etc.	Firm has submitted pictorial evidence of Lioresal 0.05mg/ml injection. However, details could not be confirmed from the picture.
11.	3.2.P.3.2	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	Firm has submitted that Innovator's literature survey recommended statement "**DO NOT AUTOCLAVE",** therefore the applied product has subjected to Sterilization by filtration process to maintain the sterility of the subjected product.
12.	3.2.P.5.1	MHRA approved formulation has pH 5.0-7.0 and while the applied formulation has pH of 5.0 to 7.5. Clarification shall be submitted in this regard.	Firm has submitted that Innovator's pH specification for Baclofen injection is between 5.0 – 7.0. However, analytical procedure for said product is followed as per United State Pharmacopoeia and the pH range given in the USP is 5.0- 7.5,

			therefore, the range was selected as per monograph. They also submitted USP monograph. They further submitted that their Finished Product Specification claim is also "USP" enclosed find updated information of Section 1.5.6 of Baclast Injection 0.05mg/ml i.e. "USP Specification" *However, in the initially submitted dossier, firm has mentioned "innovator specifications."*
13.	3.2.P.5.2	Preparation of sample solution in the assay method of analytical procedure shall be submitted.	As per USP monograph, preparation of Sample solution are as follows: **"Nominally 50 µg/mL of baclofen from Injection. Use a portion of Injection. Dilute with water, if necessary"** As per submitted SOP of 0.05mg/ml we inject direct sample, because its concentration is already 0.05mg/ml or 50ug/ml as per USP
14.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg. Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone). Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved with USP Specifications.

- **Registration letter will be issued after submission of 7500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

840.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 971 dated 11-01-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 70767779723 dated 22-09-2022.
	The proposed proprietary name / brand name	**Baclast 2mg/ml solution for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Baclofen …….. 2mg.
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	USP Specifications.

	The status in reference regulatory authorities	Baclofen 2mg/ml solution for injection, MHRA approved. 5ml ampoule contains 10mg baclofen.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	1 ampoule, 5 ampoule & 10ml ampoule.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.4	Fill volume for the applied formulation shall be submitted.	Firm has submitted that Innovator **Lioresal Intrathecal injection** is using 5ml Ampule for filling 2mg/ml. The developed product was also filled in 5ml ampule.
2.	1.5.6	This section has mentioned USP specification. Clarification shall be submitted.	Firm has submitted that their product is also USP Specification and they have also claimed the same.
3.	1.5.7	This section has mentioned IV route of administration while the reference product is intrathecal injection. Clarification shall be submitted.	Firm has submitted that it is a typographical error. Baclast Injection 2mg/ml is Intrathecal Injection.
4.	3.2.S.7.3	Stability data sheets have mentioned Assay test by HPLC while the analytical procedures have mentioned potentiometric method. Clarification shall be submitted.	Firm has submitted that drug substance manufacturer M/s Panchsheel Organics Limited stated that "There was a typographical error in the ODMF. Mistakenly the Assay was mentioned as "By HPLC" instead of "By Potentiometric Titration". They also submitted revised stability studies with Potentiometric Titration.
5.	3.2.P.2.2	Pictorial evidence of the innovator product against which PE studies are performed shall be submitted with clear details of batch number, manufacturing date and manufacturer etc.	Firm has submitted pictorial evidence of Lioresal 2mg/ml injection. Details are also visible from the picture.
6.	3.2.P.3.2	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	Firm has submitted that Innovator's literature survey recommended statement "**DO NOT AUTOCLAVE",** therefore the applied product has subjected to Sterilization by filtration process to maintain the sterility of the subjected product.
7.	3.2.P.5.1	MHRA approved formulation has pH 5.5-6.8 and while the applied formulation has pH of 5.0 – 7.5. Clarification shall be submitted in this regard.	Firm has submitted that Innovator's pH specification for Baclofen injection is between 5.0 – 7.0. However, analytical procedure for said product is followed as per United State Pharmacopoeia and the pH range given in the USP is 5.0- 7.5, therefore, the range was selected as per monograph. They also submitted USP monograph.
8.	3.2.P.5.2	Preparation of sample solution in the assay method of analytical procedure shall be submitted.	As per USP monograph, preparation of Sample solution are as follows: **"Nominally 50 µg/mL of baclofen from Injection. Use a portion of Injection. Dilute with water, if necessary"**

			Sample Solution preparation: Transfer quantitatively 5ml of sample (which is equivalent to 10mg of baclofen) in 200ml volumetric flask and make up the volume up to the mark with diluent and mix well. Filter through 0.45micron filter.
9.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg. Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone). Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for typo errors in the applications as per decision of registration Board.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

841.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 970 dated 11-01-2023.
	Details of fee submitted	Rs. 75,000/- vide slip No. 30372507344 dated 22-09-2022.
	The proposed proprietary name / brand name	**Baclast 1mg/ml solution for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Baclofen …….. 1mg.
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Gablofen 1 mg/ml solution for injection/infusion, MHRA approved. 20ml vial contains 20mg baclofen.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	1 vial.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.6	This section has mentioned USP specification. Clarification shall be submitted.	Firm has submitted that their product is also USP Specification and they have also claimed the same.

2.	1.5.7	This section has mentioned IV route of administration while the reference product is intrathecal injection. Clarification shall be submitted.	Firm has submitted that it is a typographical error. Baclast Injection 1mg/ml is Intrathecal Injection.
3.	3.2.S.7.3	Stability data sheets have mentioned Assay test by HPLC while the analytical procedures have mentioned potentiometric method. Clarification shall be submitted.	Firm has submitted that drug substance manufacturer M/s Panchsheel Organics Limited stated that "There was a typographical error in the ODMF. Mistakenly the Assay was mentioned as "By HPLC" instead of "By Potentiometric Titration". They also submitted revised stability studies with Potentiometric Titration
4.	3.2.P.2.2	Pictorial evidence of the innovator product against which PE studies are performed shall be submitted with clear details of batch number, manufacturing date and manufacturer etc.	Firm has submitted pictorial evidence of Lioresal 1mg/ml injection. However, details could not be confirmed from the picture.
5.	3.2.P.3.2	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	Firm has submitted that Innovator's literature survey recommended statement "**DO NOT AUTOCLAVE",** therefore the applied product has subjected to Sterilization by filtration process to maintain the sterility of the subjected product.
6.	3.2.P.5.1	MHRA approved formulation has pH 5.5 - 7.5 and while the applied formulation has pH of 5.0 – 7.5. Clarification shall be submitted in this regard.	Firm has submitted that Innovator's pH specification for Baclofen injection is between 5.0 – 7.0. However, analytical procedure for said product is followed as per United State Pharmacopoeia and the pH range given in the USP is 5.0- 7.5, therefore, the range was selected as per monograph. They also submitted USP monograph. They further submitted that thier Finished Product Specification claim is also "USP".
7.	3.2.P.5.2	Preparation of sample solution in the assay method of analytical procedure shall be submitted.	As per USP monograph, preparation of Sample solution are as follows: **"Nominally 50 µg/mL of baclofen from Injection. Use a portion of Injection. Dilute with water, if necessary"** As per submitted SOP of 0.05mg/ml we inject direct sample, because its concentration is already 0.05mg/ml or 50ug/ml as per USP. Transfer quantitatively 5ml of sample (which is equivalent to 5mg of baclofen) in 100ml volumetric flask and make up the volume up to the mark with diluent and mix well. Filter through 0.45micron filter. They also submitted SAP.

8.	3.2.P.8	• Stability data sheets have mentioned ampoule vial rest of the application has mentioned vial. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that it is a typo error. They further submitted corrected stability data sheets. Olagen OD Tablet (Olanzapine) 5mg, 10mg & 20mg. Zpclo Tablet 1mg, 2mg & 3mg (Eszopiclone). Exifin Infusion 600mg/100ml (Ibuprofen) approved in DRB 331.

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for typo errors in the applications as per decision of registration Board.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

842.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37341 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 2642367156 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 10mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (brivaracetam) tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets), USFDA Approved.
	For generic drugs (me-too status)	Brivatam 10mg Tablet, CCL Pharmaceuticals, Reg. No. 109737.
	Proposed Pack size	10's, 14's, 30's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm

1.	1.5	This section has not mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that by mistake they have not written film coated tablet in this section. They also submitted corrected section with each film coated tablet.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated.

Decision: Approved. Registration letter will be issued after Submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

843.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37342 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 7605251042 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 25mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (brivaracetam) tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets), USFDA Approved.

	For generic drugs (me-too status)	Brivatam 25mg Tablet, CCL Pharmaceuticals, Reg. No. 109738.
	Proposed Pack size	10's, 14's, 30's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has not mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that by mistake they have not written film coated tablet in this section. They also submitted corrected section with each film coated tablet.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated.

Decision: Approved. Registration letter will be issued after Submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

844.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37343 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 2820251354 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 50mg Tablet.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 50mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (brivaracetam) tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets), USFDA Approved.
	For generic drugs (me-too status)	Brivatam 50mg Tablet, CCL Pharmaceuticals, Reg. No. 109739.
	Proposed Pack size	10's, 14's, 30's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has not mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that by mistake they have not written film coated tablet in this section. They also submitted corrected section with each film coated tablet.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated.

Decision: Approved. Registration letter will be issued after Submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

845.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37344 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 52920613 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 75mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 75mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (brivaracetam) tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets), USFDA Approved.
	For generic drugs (me-too status)	Brivatam 75mg Tablet, CCL Pharmaceuticals, Reg. No. 109740.
	Proposed Pack size	10's, 14's, 30's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has not mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that by mistake they have not written film coated tablet in this section. They also submitted corrected section with each film coated tablet.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated.

Decision: Approved. Registration letter will be issued after Submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

846.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37345 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 451625506474 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 100mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 100mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (brivaracetam) tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets), USFDA Approved.
	For generic drugs (me-too status)	Brivatam 100mg Tablet, CCL Pharmaceuticals, Reg. No. 109741.
	Proposed Pack size	10's, 14's, 30's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has not mentioned film coated tablet. Clarification shall be submitted.	Firm has submitted that by mistake they have not written film coated tablet in this section. They also submitted corrected section with each film coated tablet.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number,	Submitted and updated.

		batch size and date of initiation shall be submitted.	

Decision: Approved. Registration letter will be issued after Submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

847.		
	Name, address of Applicant / Marketing Authorization Holder	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37340 dated 20-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 73225283378 dated 14-11-2022.
	The proposed proprietary name / brand name	**Brivari 10mg/ml Oral Solution.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Brivaracetam …… 10mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03Ax23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (Brivaracetam) oral solution, USFDA Approved.
	For generic drugs (me-too status)	Brivera Oral solution, Hilex Pharmaceuticals, Reg. No. 116112.
	Proposed Pack size	120ml, 200ml & 300ml (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (10) Pb. 2023/3750 dated 13-07-2023 issued by Food & Drugs Administration, Punjab. Valid till 12-07-2025.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.

4.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case 02: Registration applications on the basis of Export facilitation of Locally manufactured (Human) drugs on Form 5F.

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 26-05-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore** have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.
Following products are presented before the Board in light of the decision of the 133rd meeting of DRAP Authority held on 13th April 2022 for consideration.

848.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 on the basis of inspection conducted on 30-04-2019 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-8/84-Lic (Vol-V) dated 08/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33450 dated 21-11-2022.
	Details of fee submitted	PKR Rs. 30,000/- vide slip no. 4849434356 dated 24-10-2022.
	The proposed proprietary name / brand name	**Paracetamol ER Tablet 665mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Paracetamol ……. 665mg
	Pharmacotherapeutic Group of (API)	Other Analgesics and Anti-pyretic. (N02BE01)

	Pharmaceutical form of applied drug	Film coated (Extended release) tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, and 100's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Panadol Extend 665mg tablets, TGA Approved.
	For generic drugs (me-too status)	Panadol Extend 665mg tablets, GSK, Pakistan.
	Name and address of API manufacturer.	M/s Zenith Chemical Industries (Pvt.0 Ltd., Moza Donday, Jia Baga, Raiwind Road, Lahore. Copy of GMP certificate No. 75/2021-DRAP (AD-2027105-531) dated 24-09-2021 issued on the basis of inspection conducted on 14-07-2021 is submitted by the firm.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. ZPAR21-002, Mfg. date 01-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (P11-001, P11-002 & P11-003)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator product i.e. Panadol Extend 665mg tablets, B. No. JD3R, mfg. date 01-2022 manufactured by M/s GSK, Pakistan by performing quality tests Identification, Dissolution & Assay.

		Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same brand that is innovator product i.e. Panadol Extend 665mg tablets, B. No. JD3R, mfg. date 01-2022 manufactured by M/s GSK, Pakistan in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F2 values calculated are in acceptable range.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, linearity, accuracy, precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zenith Chemical Industries (Pvt.) Ltd., Moza Donday, Jia Baga, Raiwind Road, Lahore.		
API Lot No.	ZPAR21-002.		
Description of Pack (Container closure system)	Packed in Alu/PVC foil blister with leaflet in bleach board unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	PCMX-T2-22	PCMX-T3-22	PCMX-T4-22
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	05/2022	05/2022	05/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 75/2021-DRAP (AD-2027105-531) dated 24-09-2021 issued on the basis of inspection conducted on 14-07-2021 is submitted by the firm.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 36/2023-DRAP (AD-957949223) dated 28-03-2023 issued on the basis of inspection conducted on 21-03-2023.
2.	2.3	Table for literature references with correct information regarding both the drug substance and drug product shall be submitted.	Firm has submitted corrected table for literature references without submission of applicable fee.
3.	3.2.S.5	COA/details of the reference standard used in the development studies shall be submitted.	Submitted.
4.	3.2.P.2.1.	Justification shall be submitted for not performing uniformity of dosage units in the pharmaceutical equivalence studies.	Firm has submitted that they have already performed the test. They also submitted revised pharmaceutical equivalence studies with inclusion of uniformity of dosage units test.
5.	3.2.P.8	• Complete six-month stability studies for both real time and accelerated stability shall be submitted. • Documents for procurement of API shall be submitted.	Submitted. Firm has submitted copy of Invoice No. 00031/521 dated 27-05-2021 from M/s Zenith Chemical Industries (Pvt.0 Ltd.

Decision: Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PR-II/EFD) vide letter No.F.1-6/2019-PR-I (EFD) dated 06-10-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s AGP Ltd., Karachi** have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

Following products are presented before the Board in light of the decision of the 133rd meeting of DRAP Authority held on 13th April 2022 for consideration.

849.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 43/2023-DRAP (K) dated 15-06-2023 on the basis of inspection conducted on 12-06-2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2010-Lic (Vol-I) dated 30/06/2020 specifying Tablet (General) section.

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4211, dated 14/02/2023.
	Details of fee submitted	PKR 75,000/- vide slip No. 58466719 dated: 18/01/2023.
	The proposed proprietary name / brand name	**Ameeg 500mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imeglimin HCl …… 500mg
	Pharmacotherapeutic Group of (API)	Other blood glucose lowering drugs, excl. insulins. (A10BX15)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Manufacturer specification.
	Proposed Pack size	1 x 10's.
	Proposed unit price	As per DRAP approved price.
	The status in reference regulatory authorities	Twimig tablets 500mg, PMDA Japan approved.
	For generic drugs (me-too status)	N/A.
	Name and address of API manufacturer.	AMI Life Sciences (Pvt.) Ltd., Block No.82/B, ECP Road, At & Post: Kararkhadi-Tal- Padra, District: Vadodara, Gujrat, India. Copy of GMP certificate No. 19039306 dated 25-04-2019 issued on the basis of inspection conducted on 04-04-2019 & 22-04-2019 valid till 24-04-2022 issued by Food and Drug Control Administration Gujrat State, India is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. IME30010222M, Mfg. date 02-2022) and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 03 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 03 months Batches: (IME/30030522-SET-I, IME/30040622-SET-I & IME/30060622-SET-I)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator product i.e. Twemeeg 500mg Tablet, B. No. DS222, Exp. date 04-2024 manufactured by M/s Sumitomo Dainippon Pharma, Japan by performing quality tests Identification, disintegration time, Uniformity of dosage units, Dissolution, Assay and Organic impurities. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same brand that is innovator product i.e. Twemeeg 500mg Tablet, B. No. DS222, Exp. date 04-2024 manufactured by M/s Sumitomo Dainippon Pharma, Japan in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). In all the above mentioned three mediums, both comparator product and test products have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies are submitted including , System suitability, specificity, linearity, accuracy, precision, LOD, LOQ, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	AMI Life Sciences (Pvt.) Ltd., Block No.82/B, ECP Road, At & Post: Kararkhadi- Tal- Padra, District: Vadodara, Gujrat, India.		
API Lot No.	IME30010222M.		
Description of Pack (Container closure system)	Alu/PVC Blister further packed in printed unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22/057-STB/IME-TAB/01	22/058-STB/IME-TAB/02	22/059-STB/IME-TAB/03

Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	09/06/2022	09/06/2022	09/06/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19039306 dated 25-04-2019 issued on the basis of inspection conducted on 04-04-2019 & 22-04-2019 valid till 24-04-2022 issued by Food and Drug Control Administration Gujrat State, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. K-289564687894 dated 05-04-2022 mentioning Imeglimin Hydrochloride MS 06 Kg from M/s AMI Lifesciences, India. Firm has also submitted copy of commercial invoice No. EXP/I/21-22/0797 dated 22-03-2022 mentioning Imeglimin Hydrochloride MS, B. No. IME/30010222M, 06 Kg from M/s AMI Lifesciences, India. Commercial invoice is not signed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Brand name mentioned in the fee slip is Twymeeg 500mg tablet while applied brand name is some other. Clarification shall be submitted.	Firm has submitted that this is typographic error as Twymeeg is the brand name of innovator.
2.	1.6.5	Valid copy of GMP certificate of the drug substance shall be submitted.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/23044097 valid till 18-04-2025 issued by Food and Drug Control Administration Gujrat State, India is submitted.
3.	3.2.S.7.3	Complete real time and accelerated stability studies for the drug substance as per Zone Iva or Zone IVb shall be submitted.	Firm has submitted 12 months' real time stability data for the already mentioned stability batches of the drug substance and 6 month accelerated stability.

Decision: Decision: Approved.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
850.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 43/2023-DRAP (K) dated 15-06-2023 on the basis of inspection conducted on 12-06-2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2010-Lic (Vol-I) dated 30/06/2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23482, dated 22/09/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 7937213633 dated: 28/08/2023.
	The proposed proprietary name / brand name	**P-Pride 1mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride ……1mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. (A06AX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	AGP specification.
	Proposed Pack size	As approved by DRAP.
	Proposed unit price	As per DRAP approved price.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Pri-Cic 1mg tablets, Searle Company Limited, Reg. No. 116035.
	Name and address of API manufacturer.	Symed Labs Limited, Unit-I, Survey No. 353, Domadugu (Village) Gummadidala, (Mandal), Sangareddy- 502 313, Telangana, India. Copy of License No. 1/MD/AP/99/B/R dated 18-07-2023 issued by Drugs Control Administration Government of Telangana valid till 31-12-2027 is submitted.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. IPCS0040722, Mfg. date 07-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (PCS 0010216, PCS 0020316 & PCS 0030316)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Resolor 1mg Tablet, B. No. KLL1P02, Exp. date of 11-2023 manufactured by M/s Janssen-Cilag S. p. A, Italy by performing quality tests Identification, disintegration time, Uniformity of dosage units, Dissolution, Assay and Organic impurities. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same brand that is Resolor 1mg Tablet, B. No. KLL1P02, Exp. date of 11-2023 manufactured by M/s Janssen-Cilag S. p. A, Italy in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). In all the above mentioned three mediums, both comparator product and test products have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies are submitted including , System suitability, specificity, linearity, accuracy, precision, LOD, LOQ, range & robustness.
STABILITY STUDY DATA		
Manufacturer of API	Symed Labs Limited, Unit-I, Survey No. 353, Domadugu (Village) Gummadidala, (Mandal), Sangareddy- 502 313, Telangana, India.	

API Lot No.	IPCS0040722.		
Description of Pack (Container closure system)	Alu-Alu Blister 6 x 10 which is further packed in unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	044DS01	044DS02	044DS01
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	12/2022	12/2022	12/2022
Date of Initiation	19/01/2023	19/01/2023	19/01/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. L. Dis. No: 100785/TS/2023 with a subject of "List of products approved under WHO-GMP certification scheme for export purpose" wherein Prucalopride succinate IH is approved. Certificate is issued by Drugs Control Administration Government of Telangana dated 10-01-2023 valid till 08-01-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. K-230564682416 dated 24-03-2024 mentioning Baricitinib MS from M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd. *API documents are for some other API than the applied one.*
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.8	• Justification shall be submitted for not performing uniformity of dosage unit in the stability data sheets.	Firm has submitted that as per ICH & WHO, stability studies should include testing of stability indicating attributes of the FPP, i.e. those that are susceptible to change during storage and likely to influence quality, safety and/or efficacy.

		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Content uniformity is a test that evaluates the quality of the dosage of a pharmaceutical drug. Hence AGP tested content uniformity on initial testing only and not tested on stability intervals. Firm has submitted copy of Form 6 No. K-969164689574 dated 13-09-2022 mentioning 0.1kg of Prucalopride Succinate MS from M/s Symed Labs, India. Firm has also submitted copy of commercial invoice No. 22-23/EXP-504 dated 31-08-2022 mentioning 0.1kg of Prucalopride Succinate, B. no. 1PCS0040722, mfg. date of 06-2022. *However, invoice is not attested by DRAP.*

Decision: Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

851.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 43/2023-DRAP (K) dated 15-06-2023 on the basis of inspection conducted on 12-06-2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2010-Lic (Vol-I) dated 30/06/2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23481, dated 22/09/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 5187976350 dated: 28/08/2023.
	The proposed proprietary name / brand name	**P-Pride 2mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride ……2mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. (A06AX)
	Pharmaceutical form of applied drug	Film coated tablet.

	Reference to Finished product specifications	AGP specification.
	Proposed Pack size	As approved by DRAP.
	Proposed unit price	As per DRAP approved price.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Pri-Cic 2mg tablets, Searle Company Limited, Reg. No. 116036.
	Name and address of API manufacturer.	Symed Labs Limited, Unit-I, Survey No. 353, Domadugu (Village) Gummadidala, (Mandal), Sangareddy- 502 313, Telangana, India. Copy of License No. 1/MD/AP/99/B/R dated 18-07-2023 issued by Drugs Control Administration Government of Telangana valid till 31-12-2027 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. IPCS0040722, Mfg. date 07-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (PCS 0010216, PCS 0020316 & PCS 0030316)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Resolor 2mg Tablet, B. No. LBL7N01, Exp. date of 02-2024 manufactured by M/s Janssen-Cilag S. p. A, Italy by performing quality tests Identification, disintegration time, Uniformity of dosage units, Dissolution, Assay and Organic impurities. Results of both the test product and

		innovator product are comparable. Comparative Dissolution is also performed against the same brand that is Resolor 2mg Tablet, B. No. LBL7N01, Exp. date of 02-2024 manufactured by M/s Janssen-Cilag S. p. A, Italy in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). In all the above mentioned three mediums, both comparator product and test products have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies are submitted including , System suitability, specificity, linearity, accuracy, precision, LOD, LOQ, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	Symed Labs Limited, Unit-I, Survey No. 353, Domadugu (Village) Gummadidala, (Mandal), Sangareddy- 502 313, Telangana, India.		
API Lot No.	IPCS0040722.		
Description of Pack (Container closure system)	Alu-Alu Blister 6 x 10 which is further packed in unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	045DS01	045DS02	046DS01
Batch Size	3500 Tablets	3500 Tablets	3500 Tablets
Manufacturing Date	12-200	12-200	12-200
Date of Initiation	19/01/2023	19/01/2023	19/01/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. L. Dis. No: 100785/TS/2023 with a subject of "List of products approved under WHO-GMP certification scheme for export purpose" wherein Prucalopride succinate IH is approved. Certificate is issued by Drugs Control Administration Government of Telangana dated 10-01-2023 valid till 08-01-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. K-230564682416 dated 24-03-2024 mentioning Baricitinib MS from M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd. API documents are for some other API than the applied one.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.8	• Justification shall be submitted for not performing uniformity of dosage unit in the stability data sheets.	Firm has submitted that as per ICH & WHO, stability studies should include testing of stability indicating attributes of the FPP, i.e. those that are susceptible to change during storage and likely to influence quality, safety and/or efficacy. Content uniformity is a test that evaluates the quality of the dosage of a pharmaceutical drug. Hence AGP tested content uniformity on initial testing only and not tested on stability intervals.
		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of Form 6 No. K-969164689574 dated 13-09-2022 mentioning 0.1kg of Prucalopride Succinate MS from M/s Symed Labs, India. Firm has also submitted copy of commercial invoice No. 22-23/EXP-504 dated 31-08-2022 mentioning 0.1kg of Prucalopride Succinate, B. no. 1PCS0040722, mfg. date of 06-2022. *However, invoice is not attested by DRAP.*
		• Stability data sheets as per decision of registration board with inclusion of API lot number, manufacturing date, batch size & date of initiation etc. shall be submitted.	Submitted.

Decision: Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PR-II/EFD) vide letter No.F.1-6/2019-PR-I (EFD) dated 13-09-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s Pharmatec Pakistan (Pvt.) Ltd., Karachi** have achieved the benchmark of more than 100,000 USD during the fiscal Year 2022-2023 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

Following products are presented before the Board in light of the decision of the 133rd meeting of DRAP Authority held on 13th April 2022 for consideration.

852.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, S.I.T.E.

		Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 32/2022-DRAP (K) dated 25-02-2022 issued on the basis of inspection conducted on 11-10-2021.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 2-48/84-Liv (Vol-V) dated 29-09-2020 mentioning liquid general section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No. 18430 dated 21-07-2023.
	Details of fee submitted	PKR 75,000/-: vide slip No. 9822981472 dated 21-11-2022.
	The proposed proprietary name / brand name	**Reltus-N Dry Cough Night Syrup.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Syrup contains; Diphenhydramine HCl ……...……14mg Dextromethorphan Hydrobromide ……6.5mg Levomenthol ……..…2mg
	Pharmaceutical form of applied drug	Syrup.
	Pharmacotherapeutic Group of (API)	Diphenhydramine HCl (R06AA Amino alkyl ethers) Dextromethorphan Hydrobromide (R05DA Opium alkaloids and derivatives) Levomenthol
	Reference to Finished product specifications	In-house specifications.
	Proposed Pack size	30ml, 60ml, 90ml, 120ml, 125ml & 150ml.
	Proposed unit price	As per DPC and SRO.
	The status in reference regulatory authorities	Benylin Dry Coughs Night Syrup, MHRA approved. Each 5 ml contains: Diphenhydramine hydrochloride 14 mg Dextromethorphan hydrobromide 6.5 mg Levomenthol 2 mg Benylin Dry Coughs Syrup Diphenhydramine hydrochloride 14mg/5ml Dextromethorphan hydrobromide 6.5mg/5ml Levomenthol 2mg/5ml, HPRA approved.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**<u>Diphenhydramine HCl:</u>** Qidong Dongyue Pharmaceutical Co., Ltd., No. 268 Shanghai Rd., Binjiang Fine Chemical Industry Zone, Qidong City. **<u>Dextromethorphan Hydrobromide:</u>**

		M/s Divi's Laboratories Limited, Lingojigudem village, Choutuppal Mandal, Yadadri Bhuvanagiri District Telangana, India. **Levomenthol:** M/s Anhui Great Nation Essential Oils Co., Ltd., No. 37 Xinyang Road Economy and Technology Development District, Fuyang City, Anhui Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of all the three drug substance and drug product is submitted.
	Module III (Drug Substance)	**Diphenhydramine HCl:** Firm submitted detail of drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (B. No. DH-201912401, mfg. date 11 - 2019) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dextromethorphan Hydrobromide:** Firm submitted detail of drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (B. No. S-A-0101020, mfg. date 10 - 2020) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Levomenthol:** Firm submitted detail of drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (B. No. 2004062, mfg. date 06-04-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	**Diphenhydramine HCl:** Stability study conditions and batches: Real time: 30°C ± 2°C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 06 months Batches: (DH-201701501, DH-201701502 & DH-

		201701503) **Dextromethorphan Hydrobromide:** Stability study conditions and batches: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Batches: (S-4011210, S-4021210 & S-4031210) **Levomenthol:** Not submitted.
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator Brand i.e. Benylin Dry Coughs Night Syrup manufactured by McNeil Products Limited by performing quality tests of appearance and assay content for all the three ingredients.
	Analytical method validation/verification of product	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.

STABILITY STUDY DATA

Manufacturer of API	**Diphenhydramine HCl:** Qidong Dongyue Pharmaceutical Co., Ltd., No. 268 Shanghai Rd., Binjiang Fine Chemical Industry Zone, Qidong City. **Dextromethorphan Hydrobromide:** M/s Divi's Laboratories Limited, Lingojigudem village, Choutuppal Mandal, Yadadri Bhuvanagiri District Telangana, India. **Levomenthol:** M/s Anhui Great Nation Essential Oils Co., Ltd., No. 37 Xinyang Road Economy and Technology Development District, Fuyang City, Anhui Province, China.		
API Lot No.	Diphenhydramine HCl (DH-201912401). Dextromethorphan Hydrobromide (S-A-0101020-3) Levomenthol (2004062) Sodium benzoate (20200619-4 & 20200619-5)		
Description of Pack (Container closure system)	Amber glass bottle packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD133DMDS03	21PD134DMDS04	21PD138DMDS05
Batch Size	05 Liters	05 Liters	10 Liters
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	16-05-2022	16-05-2022	16-05-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Diphenhydramine HCl:** Qidong Dongyue Pharmaceutical Co., Ltd., No. 268 Shanghai Rd., Binjiang Fine Chemical Industry Zone, Qidong City. Firm has submitted copy of License No. SU20160261 dated 17-09-2020 valid till 16-09-2025. **Dextromethorphan Hydrobromide:** M/s Divi's Laboratories Limited, Lingojigudem village, Choutuppal Mandal, Yadadri Bhuvanagiri District Telangana, India. **Levomenthol:** M/s Anhui Great Nation Essential Oils Co., Ltd., No. 37 Xinyang Road Economy and Technology Development District, Fuyang City, Anhui Province, China. Copy of certificate No. CN14/21092 issued by SGS mentioning the M/s Anhui Great Nation Essential Oils Co., Ltd., has been assessed and certified as meeting the requirements of ISO 22000:2018 valid till 24-09-2023 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Diphenhydramine HCl:** Firm has submitted copy of FedEx courier. However, firm has not submitted any attested invoice or any form 6 etc. **Dextromethorphan Hydrobromide:** Firm has submitted copy of commercial invoice No. ZHI-CI/5063/1220 dated 01-12-2020 mentioning 100kg of dextromethorphan HBr, Batch No. S-A-0101020. Invoice is attested by Assistant Director, DRAP, Karachi dated 28-01-2021. **Levomenthol:** firm has not submitted any attested invoice or any form 6 etc.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm

1.	1.6.5	• Valid copy of GMP certificate for drug substance Dextromethorphan Hydrobromide issued by concerned/relevant regulatory authority shall be submitted. • GMP certificate for Levomenthol has mentioned Food grade. Justification shall be submitted regarding food grade oil used in pharmaceutical formulation. • Valid copy of GMP certificate for drug substance Levomenthol issued by concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. 87971/TS/2022 dated 05-05-2022 issued by Drugs Control Administration, Telangana valid till 03-05-2025. Firm has submitted that People republic of China is not issuing the GMP certificate of states, therefore, GMP certificate of Levomenthol from Anhui great national Essential Oils Co., Ltd, cannot be provided. In place of GMP certificate they provided a certificate of SGS certificate, Kosher certificate etc. *However, firm has not submitted any justification regarding food grade oil used in pharmaceutical formulation.*
2.	2.3	Table for literature references with correct information regarding the drug substances with applicable fee shall be submitted.	Submitted. Applicable fee is not submitted.
3.	3.2.S.4.2	• Justify the difference in the Standard concentration and sample concentration of Dextromethorphan HBr analytical method with respect to the Standard concentration and sample concentration of Dextromethorphan HBr in USP monograph. • Evidence of availability of GC and flame ionization detector for the testing of Levomenthol shall be submitted.	Firm has submitted that we reviewed the method and identified a typographical error in the testing procedure. Specifically, in the preparation of working standard solution and working sample solution. We inadvertently pipetted out 15ml of solution instead of the correct 10ml of stock standard solution and sample solution. The errors have been rectified in the standard testing method and submitted. Additionally, we have re-performed complete testing of dextromethorphan HBr Batch #S-A-0101020 as per revised method and obtained results are approximately same as initial results. The attached analytical test report provides evidence of these results. Furthermore, the attached analytical method verification of API dextromethorphan HBr fulfills all the requirements of the USP monograph for dextromethorphan HBr. Firm has submitted Protocol and report for GC.
4.	3,2.S.5	• COA/details of the reference/working standard used in the development of	Submitted.

		trial batches for diphenhydramine HCl shall be submitted. • COA/details of the reference/working standard used in the development of trial batches for Levomenthol shall be submitted.	Submitted.
5.	3.2.S.7	• Stability data sheets for Diphenhydramine HCl with stability conditions shall be submitted. • Stability data sheets for Levomenthol with stability conditions for both real time and accelerated stability shall be submitted.	Submitted. Submitted. *However, it is only table without any name of the company and signatures.*
6.	3.2.P.2.2	• Justification shall be submitted for not performing most of the tests in the PE studies. • Pictorial evidence of the innovator product with visible details of batch number, manufacturing date etc. shall be submitted.	Firm has submitted that during the trial batch manufacturing, we conducted assays for the active substance, pH, and specific gravity tests on the innovator product (Benylin Dry Cough Night Syrup, batch # M1268R, expiry 03-2022), and submitted the results to DRAP. Subsequently, during the preparation of our stability batches, we performed comprehensive testing, comparing it with the innovator product Benylin Dry Cough Night Syrup, batch # T3421R, expiry 08-2023). Firm has also submitted complete reports and pictorial evidence of the innovator product with visible details.
7.	3.2.P.5.2	• Stock sample solution has mentioned 5gm of sample solution. However, quantity of each ingredient could not be confirmed from 5gm as the label claim is in ml. clarification shall be submitted.	Firm has submitted that there might be a typo error in the testing method. As per our method we pipette out 5mL of the sample, then weigh and transfer it to achieve more accurate results. This approach, using sample weight in grams instead of millimeters, is preferred because weight measurements are generally considered more accurate and reproducible than volume measurements. Subsequently, specific gravity is utilized in the calculation to further enhance the accuracy of the results. As you can See in the calculation method "V" represents volume with a nominal value of 5ml. They also submitted revised method with correction.
8.	3.2.P.8	• Stability data sheets have mentioned different batch number for Dextromethorphan Hydrobromide than mentioned in 3.2.S.4.4. Clarification shall be submitted.	Firm has submitted that it was a typo error. They also submitted revised stability data sheets wherein they have corrected API lot number from S-A-0101020-3 to S-A-0101020.

		• Documents for the procurement of API with approval from DRAP for Levomenthol and Diphenhydramine HCl (in case of import) shall be submitted.	Firm has submitted Sales Tax Invoice No. K-106989 dated 15-12-2020 from supplier M/s Brothers Enterprises (Pvt.) Ltd., However, no clearance certificate from DRAP is submitted by the firm. Firm has submitted that Diphenhydramine HCl from Qidong Dongyue Pharmaceutical Co., Ltd. Used in the manufacturing of trial batches were procured free of cost. They also provided courier slip. However, no clearance certificate from DRAP is submitted by the firm.

Decision: Deferred for following;

- **Submission of full fee i.e. 30,000/- for more than two typo errors in the application as per decision of Registration Board shall be submitted.**
- **Justification shall be submitted regarding food grade oil used in pharmaceutical formulation.**
- **Valid copy of GMP certificate for drug substance Levomenthol issued by concerned/relevant regulatory authority shall be submitted.**
- **Stability data sheets for Levomenthol from the drug substance manufacturer with stability conditions for both real time and accelerated stability shall be submitted.**
- **Documents for the procurement of API with approval from DRAP for Levomenthol and Diphenhydramine HCl (in case of import) shall be submitted.**

Case 03: Registration applications on the basis of Export facilitation of Locally manufactured (Human) drugs on Form 5D.

853.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Cholicin 5mg Tablet.
	Diary No. Date of R& I & fee	Dy. No. 32413, R&I Dated 28.09.2018. **(Duplicate dossier)**, Rs. 50,000/- vide slip No. 0755041 dated 28-09-2018. R&I section DRAP has verified the Dy. No. and date.
	Composition	Each film-coated tablet contains: Obeticholic acid ……..…..... 5mg
	Pharmacological Group	Farnesoid X-receptor agonist.
	Type of Form	Form 5D.
	Finished Product Specification	Manufacturers specification
	Pack size & Demanded Price	10's & as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ocaliva 5mg & 10mg tablet by Intercept Pharma, USFDA approved.
	Me-too status	Abeticolic 5mg tablets, M/s Dyson Research laboratory, Reg. No. 109521.
	GMP status	Copy of GMP certificate No. 43/2023-DRAP (K) dated 15-06-2023 on the basis of inspection conducted on 12-06-2023 is submitted.

STABILITY STUDY DATA	
Drug	Cholicin 5mg Tablet.
Name of Manufacturer	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Jintang Industrial Park, Shaowu City, Fujian Province, China.

API Lot No.	210301.		
Description of Pack (Container closure system)	Alu-Alu blister pack of 3 x 10's further packed in printed unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	21/079-STB/OBE-Tab/01	21/080-STB/OBE-Tab/02	21/081-STB/OBE-Tab/03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablet
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	27-01-2022	27-01-2022	27-01-2022
No. of Batches	03		
Date of Submission	21-11-2022 (Dy. No. 33452)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT FOR EXEMPTION

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

S. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their last inspection report for their product "Glyzia XR tablet" Registration Board in its 285th meeting decided to approve Registration of "Glyzia XR tablet by M/s AGP Limited, Karachi. Date of Inspection: 26-09-2018. Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted COA of Obeticholic acid (Batch # 210301) from M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China. COA from M/s AGP Limited with same batch number is also submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 months & long term, 12 months stability study reports of 03 batches (171001, 171002 & 171003).
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. FJ20160009 of M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China issued by China Food and Drug Administration. The certificate is valid till 22-02-2021. Firm has also submitted copy of License No. 20160119 valid till 04-09-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of commercial invoice No. WIS210019 dated 12-03-2021mentioning 0.55kg of Obeticholic acid. Invoice is also attested by Assistant Director, DRAP, Karachi dated 19-03-2021. Firm has also submitted attested copy of form 6

<table>
<tr><td></td><td></td><td>attested by Assistant Director, DRAP, Karachi dated 19-03-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted that all ingredients are used same as reference product which provides compatible stability studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has manufactured three stability batches of Obeticholic acid 5mg Tablets and has submitted copy of complete batch manufacturing. Details are as under:
<table>
<tr><td colspan="3">Cholicin 5mg tablet.</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Date</td></tr>
<tr><td>21/079-STB/OBE-Tab/01</td><td>5000 Tablets</td><td>12-2021</td></tr>
<tr><td>21/080-STB/OBE-Tab/02</td><td>5000 Tablets</td><td>12-2021</td></tr>
<tr><td>21/081-STB/OBE-Tab/03</td><td>5000 Tablets</td><td>12-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP against Abeticolic 5mg tablets, B. No. DY001, mfg. date of 10-2021 manufactured by Dyson Research Laboratory in three different mediums i.e. 0.1N HCl, Acetate Buffer pH 4.5 & Phosphate Buffer pH 6.8. In first two medium no release is observed while in Phosphate buffer pH 6.8 F_2 is in acceptable range.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
</table>

Remarks of the Evaluator:

Sr. No.	Observations	Submission by the firm.
1	Approval of API/ DML/ valid GMP certificate of drug substance manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of license No. 20160119 for M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China valid till 10-08-2026.
2	Method used for analysis of API from Finished Product manufacturer shall be submitted.	Submitted.
3	Submitted method of analysis for drug substance from drug substance manufacturer has no sample and standard preparation method in assay test.	Firm has submitted analytical procedures wherein they have mentioned sample and standard preparation methods for the assay test in the analytical method.
4	Stability data sheets with stability condition shall be submitted.	Firm has submitted stability data sheets with accelerated stability condition of 25˚C ± 2˚C / 60% ± 5%RH for 06 months and real time

		condition of 5 ± 3°C for 12 months.
5	Justification for not performing CDP against the innovator product shall be submitted.	Firm has submitted that innovator product is not available in the local market, and we could not import this medicine because this falls under the prescription drug category. They further submitted that as per DRAP, frequently asked questions about form 5F, Q-23, CDP performed against comparator product available in Pakistan is acceptable with justification. So in this regard local brand available manufactured by M/s Dyson Research Laboratories, which is easily available and approved by DRAP is taken as reference product during performing of dissolution profile.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

854.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Cholicin 10mg Tablet.
	Diary No. Date of R& I & fee	Dy. No. 32414, R&I Dated 28.09.2018. **(Duplicate dossier),** Rs. 50,000/- vide slip No. 0755042 28-09-2018. R&I section DRAP has verified the Dy. No. and date.
	Composition	Each film-coated tablet contains: Obeticholic acid ……..…..... 10mg
	Pharmacological Group	Farnesoid X-receptor agonist.
	Type of Form	Form 5D.
	Finished Product Specification	Manufacturers specification
	Pack size & Demanded Price	10's & as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ocaliva 5mg & 10mg tablet by Intercept Pharma, USFDA approved.
	Me-too status	Abeticolic 10mg tablets, M/s Dyson Research laboratory, Reg. No. 109522.
	GMP status	Copy of GMP certificate No. 43/2023-DRAP (K) dated 15-06-2023 on the basis of inspection conducted on 12-06-2023 is submitted.

STABILITY STUDY DATA	
Drug	Cholicin 10mg Tablet.
Name of Manufacturer	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Jintang Industrial Park, Shaowu City, Fujian Province, China.
API Lot No.	210301.
Description of Pack (Container closure system)	Alu-Alu blister pack of 3 x 10's further packed in printed unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)

Batch No.	22/002-STB/OBE-Tab/04	22/003-STB/OBE-Tab/05	22/004-STB/OBE-Tab/06
Batch Size	5000 Tablets	5000 Tablets	5000 Tablet
Manufacturing Date	01-2022	12-2021	12-2021
Date of Initiation	27-01-2022	27-01-2022	27-01-2022
No. of Batches	03		
Date of Submission	21-11-2022 (Dy. No. 33451)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT FOR EXEMPTION

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

S. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their last inspection report for their product "Glyzia XR tablet" Registration Board in its 285th meeting decided to approve Registration of "Glyzia XR tablet by M/s AGP Limited, Karachi. Date of Inspection: 26-09-2018. Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted COA of Obeticholic acid (Batch # 210301) from M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China. COA from M/s AGP Limited with same batch number is also submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 months & long term, 12 months stability study reports of 03 batches (171001, 171002 & 171003).
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. FJ20160009 of M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China issued by China Food and Drug Administration. The certificate is valid till 22-02-2021. Firm has also submitted copy of License No. 20160119 valid till 04-09-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of commercial invoice No. WIS210019 dated 12-03-2021mentioning 0.55kg of Obeticholic acid. Invoice is also attested by Assistant Director, DRAP, Karachi dated 19-03-2021. Firm has also submitted attested copy of form 6 attested by Assistant Director, DRAP, Karachi dated 19-03-2021.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted that all ingredients are used same as reference product which provides compatible stability studies.

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has manufactured three stability batches of Obeticholic acid 5mg Tablets and has submitted copy of complete batch manufacturing. Details are as under:
<table>
<tr><td colspan="3">Cholicin 5mg tablet.</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Date</td></tr>
<tr><td>22/002-STB/OBE-Tab/04</td><td>5000 Tablets</td><td>01-2022</td></tr>
<tr><td>22/002-STB/OBE-Tab/05</td><td>5000 Tablets</td><td>01-2022</td></tr>
<tr><td>22/002-STB/OBE-Tab/06</td><td>5000 Tablets</td><td>01-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP against Abeticolic 10mg tablets, B. No. DZ001, mfg. date of 10-2021 manufactured by Dyson Research Laboratory in three different mediums i.e. 0.1N HCl, Acetate Buffer pH 4.5 & Phosphate Buffer pH 6.8. In first two medium no release is observed while in Phosphate buffer pH 6.8 F_2 is in acceptable range.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
</table>

Remarks of the Evaluator:

Sr. No.	Observations	Submission by the firm.
1	Approval of API/ DML/ valid GMP certificate of drug substance manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of license No. 20160119 for M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., China valid till 10-08-2026.
2	Method used for analysis of API from Finished Product manufacturer shall be submitted.	Submitted.
3	Submitted method of analysis for drug substance from drug substance manufacturer has no sample and standard preparation method in assay test.	Firm has submitted analytical procedures wherein they have mentioned sample and standard preparation methods for the assay test in the analytical method.
4	Stability data sheets with stability condition shall be submitted.	Firm has submitted stability data sheets with accelerated stability condition of 25˚C ± 2˚C / 60% ± 5%RH for 06 months and real time condition of 5 ± 3˚C for 12 months.
5	Justification for not performing CDP against the innovator product shall be submitted.	Firm has submitted that innovator product is not available in the local market, and we could not import this medicine because this falls under the prescription drug category. They further submitted that as per DRAP, frequently asked questions about form 5F, Q-23, CDP performed against comparator product available in Pakistan is acceptable with justification. So in this regard local brand available manufactured by M/s Dyson Research Laboratories, which is easily available and approved by DRAP is taken as reference product

		during performing of dissolution profile.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

Case No. 04. Registration applications of locally manufactured deferred applications on form 5F.

855.	Name, address of Applicant / Marketing Authorization Holder	**M/s Daneen Pharma (Pvt.) Ltd., Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, Lahore (Contract giver).** **M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road Karachi (Contract acceptor).**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road Karachi (Contract acceptor).
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 46/2021-DRAP (K) dated 07-10-2021 on the basis of inspection conducted on 15-06-2021 is submitted for M/s Genix Pharma.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 mentioning Dry Powder Injection General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18960, dated 29/06/2022.
	Details of fee submitted	PKR 75,000/- vide slip No. 73873806 dated: 10/06/2022.
	The proposed proprietary name / brand name	**Espra 40mg powder for injection/infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole Sodium eq. to Esomeprazole…….. 40mg.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Pharmaceutical form of applied drug	Powder for injection.
	Reference to Finished product specifications	Manufacturer specification.
	Proposed Pack size	10’s.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Nexium IV 40mg, USFDA Approved.
	For generic drugs (me-too status)	Nexum IV 40mg Injection, Getz Pharma, Reg. No. 050651.
	Name and address of API manufacturer.	M/s Rajasthan Antibiotics Limited, Address: Unit-II, A-619 & 630, RIICO Industrial Area, Bhiwadi – 301 019, District - Alwar, Rajasthan, India.

		Copy of GMP certificate No. DC/A-1/GMP/2022/439 dated 10-03-2022 issued by Drugs Control Administration Rajastan wherein on the basis of inspection conducted on 11-01-2022 previous GMP certificate is extended up to 22-01-2023. ***Not valid.***
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, Solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. AESS19006, Mfg. date 01-02-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches; AESS15001, AESS15002 & AESS15003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Nexum 40mg injection, B. No. 148P07 manufactured by Getz Pharma Pakistan (Pvt.) Ltd., by performing quality tests Identification, fill weight & Assay.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, linearity, accuracy, precision, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	M/s Rajasthan Antibiotics Limited, Address: Unit-II, A-619 & 630, RIICO Industrial Area, Bhiwadi – 301 019, District - Alwar, Rajasthan, India.
API Lot No.	Not submitted.
Description of Pack (Container closure system)	Clear glass vial Type I further packed in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0,3,6, 9, 12 (Months)		
Batch No.	010I043	011I043	012I043
Batch Size	8358 vials	8637 vials	8443 vials
Manufacturing Date	12-2020	03-2021	06-2021
Date of Initiation	29-12-2020	31-03-2021	30-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. DC/A-1/GMP/2022/439 dated 10-03-2022 issued by Drugs Control Administration Rajasthan wherein on the basis of inspection conducted on 11-01-2022 previous GMP certificate is extended up to 22-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-669480622714 dated 05-04-2022 specifying 5.0Kg of Esomeprazole Sodium Sterile with batch No. AESS21009, mfg. date of 01-01-2022. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	*Not submitted.*
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. DC/A-1/WHO-GMP/2023/931 dated 22-02-2023 valid for a period of 03 years.
3.	2.3	Table for literature references of the drug substance has mentioned drug substance in BP. Clarification shall be submitted. Revised table for literature references with correct information regarding the	Firm has submitted revised table with correct information with submission of 7500/- fee vide slip No. 4468179036 dated 05-10-2023.

		drug substance and applicable fee shall be submitted.	
4.	3.2.S.4.2	Injection volume provided by the drug substance manufacturer has mentioned 20µl while drug product manufacturer has mentioned 10 µl. clarification shall be submitted.	Firm has submitted that they used 10ul injection volume to enhance column efficiency and avoid from overloading.
5.	3.2.S.4.3	Analytical method verification studies including Accuracy, Specificity and precision along with details shall be submitted.	Submitted.
6.	3.2.S.7	• Justification shall be submitted for over writing/altering the Humidity condition i.e. RH 65% ± 5% in the real time stability data of the drug substance. • Real time stability data sheets for the drug substance as per zone Iva condition shall be submitted.	*No justification is submitted against this point.* *Firm has submitted new stability data sheets for the drug substance both at real time and accelerated stability.* Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches; AESS15001, AESS15002 & AESS15003.
7.	3.2.P.2.2	• Justification shall be submitted for not performing PE against the innovator brand. • Justification shall be submitted for not performing sterility, Bacterial endotoxin and particulate matter tests in pharmaceutical equivalence studies. • Justification shall be submitted for not performing pH of the reconstituted solution in pharmaceutical equivalence studies.	Firm has submitted that because of the absence of an innovator sample, CDP was performed using the local competitor sample in accordance with section 3 of WHO Technical Report Series Number 992, 2015, "Guidance of the Selection of Comparative Pharmaceutical Products for Equivalence Assessment of Interchangeable Multi-Source (Generic) Products." General Principle 1: In profile with that of comparator products Tablets, for which a national marketing authorization has been given. Firm has replied that these tests already performed in PE study and provided updated report for pharmaceutical equivalence wherein they added these tests. Same reply as above.
8.	3.2.P.5.1	Justification shall be submitted for not including pH of the reconstituted solution in the specifications.	Firm has provided revised finished product specifications wherein they added pH of the reconstituted solution in the specifications.
9.	3.2.P.8	• Specification has mentioned filled weight of 113 ± 7% while the stability data sheets have mentioned 118.44 ± 7%. Clarification shall be submitted. • Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number shall be submitted. • Documents for procurement of API of the same batch from which batches are manufactured shall be submitted.	Firm has provided updated SOP for finished product specifications wherein they revised fill volume. Firm has submitted stability data sheets with inclusion of API lot No. AESS19006. Firm has submitted copy of invoice No. RAL2E/20-21/0183 dated 03-03-2021 specifying 4.0Kg of Esomeprazole Sodium

		• Clearance certificate provided is cleared on 05-04-2022 while the batches are manufactured in December, 2020, March 2021 & June 2021 respectively. Justification shall be submitted. • Raw data sheets for calculation of assay test and dissolution test shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Sterile with batch No. AOSS20030, mfg. date of 11-2020 & batch No. AESS20003, mfg. date of 12-2020. The invoice is cleared by AD (I&E) DRAP, Karachi dated 26-03-2021. API lot number used in the manufacturing of batches is different from that of the clearance document. Submitted. ***N/A.***

Decision of 331st meeting of Registration Board.: Deferred for submission of documents for procurement of API of the same batch from which batches are manufactured, with approval from DRAP, shall be submitted.

Reply submitted by the firm:

Firm has submitted that in finished product with batch No. 011I043, API with lot number AESS19006 was used. They also submitted copy of invoice No. RAL3E/20-21/0174 dated 10-03-2020 mentioning 02kg of Esomeprazole lyophilized powder with batch No. AESS19006, mfg. date of 02-2020. The invoice is attested by Assistant Director, DRAP, Karachi dated 03-04-2020. They also submitted COAs from both drug substance and drug product manufacturer.

Firm has further submitted that in finished product with batch No. 012I043, API with lot number AESS20003 was used. They also submitted copy of invoice dated 03-03-2021 mentioning 02kg of Esomeprazole lyophilized powder with batch No. AESS20003, mfg. date of 12-2020. The invoice is attested by Assistant Director, DRAP, Karachi dated 26-03-2021. They also submitted COAs from both drug substance and drug product manufacturer.

Firm has further submitted that in finished product with batch No. 010I043, API with lot number SI/EPZ/00041118 was used. They also submitted copy of commercial invoice No. E/168/SIPL/18-19 dated 19-12-2018 mentioning 05kg of Esomeprazole sodium sterile (lyophilized powder) with batch No. SI/EPZ/00041118, mfg. date of 11-2018. The invoice is attested by Assistant Director, DRAP, Karachi dated 03-01-2019. They also submitted COAs from both drug substance and drug product manufacturer.

Remarks of the evaluator.

Finished product with batch No. 010I043 wherein API with lot number SI/EPZ/00041118 is used has mentioned the name of manufacturer as Sterile India Pvt., Ltd., while in the submitted data at the time of Form 5F there are no details of this manufacturer. No information for this source is submitted by the firm I.e. Details of the manufacturing site, COAs of the drug substance, stability data for the drug substance as per Zone Iva, analytical method and its verification etc.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

856.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry Powder suspension (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14708 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 9880312550 Dated 05-06-2023.
	The proposed proprietary name / brand name	**Ampiwell Dry Powder Suspension 125mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ampicillin as trihydrate …… 125mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	60ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ampicillin 125 mg/5ml Oral Suspension, Kent Pharmaceuticals Limited, MHRA Approved.
	For generic drugs (me-too status)	Ampcin 15 mg Dry Suspension, CSH Pharmaceuticals, Reg. No. 071538.
	Name and address of API manufacturer.	M/s Zafa Chemie, Raiwind Road Bypass, Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore, Pakistan. Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 828, mfg. date 02-2021) and

		justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Real time: B. No. 804, 805 & 806. Accelerated: 808, 809 & 810.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Ampicillin dry powder suspension with B. No. SM-022, mfg. date 05-2022 manufactured by M/s Amros Pharmaceuticals by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zafa Chemie, Raiwind Road Bypass, Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore, Pakistan.		
API Lot No.	828.		
Description of Pack (Container closure system)	Amber colour glass sealed labelled bottle securely packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	16-08-2022	16-08-2022	16-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has once again submitted Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019. *Not within last three years.*
2.	2.3	Table for literature references with correct information shall be submitted.	Firm has provided corrected information with submission of 7500/- fee vide slip No. 22193240162 dated 10-07-2023.
3.	3.2.S.7	Real time and accelerated stability study data of the drug substance for the same batches shall be submitted.	*Firm has once again submitted real time stability data of the drug substance for the same batches.* *Real time: B. No. 804, 805 & 806.* *Accelerated: 808, 809 & 810.* *Stability study data for same batches is not provided.*
4.	3.2.P.2.2	Justification for not performing the pharmaceutical equivalence test against the innovator product.	Firm has submitted that innovator product was not available in the market, so they used competitor product.
5.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Justification shall be submitted for the applied wavelength (230) in the submitted chromatograms with respect to the analytical procedures and BP (254). • Justification shall be submitted for the injection volume (20) in the submitted chromatograms with respect to the analytical procedures and BP (50µl).	Firm has submitted revised stability data sheets wherein they have included API lot number in the stability data sheets. Firm has submitted that wavelength of 230nm was adopted from USP monograph of Ampicillin. *However, finished product specifications, analytical procedures have mentioned BP specifications.* Firm has submitted that to achieve system suitability, they used 20 µl injection volume as per USP <621>, method verification also has been conducted for this variation. They further submitted that at 11-month time point they had tested by using 50 µl injection volume and using 254 nm wavelength and found satisfactory results.

		• Raw data sheets for calculation of ampicillin content at each time point shall be submitted. • Documents for procurement of API shall be submitted.	Firm has submitted that they attached raw data sheets for calculation of ampicillin content. *However, they have not submitted any calculation sheets.* Firm has submitted copy of invoice No. 293913 mentioning 10kg quantity of Ampicillin trihydrate with batch No. 828.

Decision of 330th meeting of Registration Board: Deferred for following;

- Valid copy of GMP certificate/inspection report conducted within last three years of the drug substance manufacturer shall be submitted.
- Real time and accelerated stability study data of the drug substance for the same batches shall be submitted.
- Pharmaceutical equivalence test of the applied formulation against the innovator product shall be submitted.
- Justification shall be submitted for adopting wavelength (230nm) in the submitted chromatograms while the specification and analytical procedures of the finished product has mentioned BP specification with wavelength of (254nm).
- Raw data sheets for calculation of ampicillin content at each time point shall be submitted.

Submission by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Valid copy of GMP certificate/inspection report conducted within last three years of the drug substance manufacturer shall be submitted.	Firm has submitted copy of letter dated 02-11-2020 wherein M/s Zafa Chemie has applied for renewal of DML No. 000589 endorsed in DRAP dated 05-11-2020. *However, Neither valid copy of GMP certificate nor valid copy of DML is submitted by the firm.*
2.	Real time and accelerated stability study data of the drug substance for the same batches shall be submitted.	Firm has submitted stability data of drug substance for both real time and accelerated for same batches i.e. 818, 819 & 820
3.	Pharmaceutical equivalence test of the applied formulation against the innovator product shall be submitted.	Firm has submitted that innovator reference product is not available in market, so they have performed PE studies with competitor reference pack i.e. Ampicillin dry powder suspension, B. no. SM-022, mfg. date 05-2022 manufactured by Amros pharmaceutical, Karachi.
4.	Justification shall be submitted for adopting wavelength (230nm) in the submitted chromatograms while the specification and analytical procedures of the finished product has mentioned BP specification with wavelength of (254nm).	Firm has submitted that wavelength of 230nm was adopted from USP monograph of Ampicillin. Product analytical method had been updated as per BP specifications and testing at 12 month time point is carried out at 254nm wavelength.
5.	Raw data sheets for calculation of ampicillin content at each time point shall be submitted.	Submitted.

Decision: Approved. Registration letter will be issued after submission of valid DML of the drug substance manufacturer.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

857.	**Name, address of Applicant / Marketing Authorization Holder**	Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate, Hattar.

	Name, address of Manufacturing site.	Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted inspection report of 2018. Not valid.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6132 dated 07-03-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 775153307584 Dated 24/01/2022.
	The proposed proprietary name / brand name	**Wonowrd 10mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate 10mg
	Pharmacotherapeutic Group of (API)	Anti-ulcerative, Proton Pump Inhibitor.
	Pharmaceutical form of applied drug	Oral tablet.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	3 x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Takecab 10 mg Tablets by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Vonopran 10mg tablets, Shaigan Pharmaceuticals, Reg. No. 110800.
	Name and address of API manufacturer.	Xianqiang Pharmaceutical Pvt. Ltd., No. 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou city, Guangdong Province, China. Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (TAK09R210101, mfg. date 04-01-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. TAK09R150701, TAK09R150702 & TAK09R150703.
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the comparator product i.e. Vonozan 10mg tablets, B. No. 001FF8, mfg. date 05-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, weight variation, Disintegration, Dissolution & Assay). CDP has been performed against the same brand that is Vonozan 10mg tablets, B. No. 002FF8, mfg. date 05-2021 manufactured by M/s Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API	Xianqiang Pharmaceutical Pvt. Ltd., No. 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou city, Guangdong Province, China.		
API Lot No.	VZ20190302.		
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	900 Tablets.	900 Tablets.	900 Tablets.

Manufacturing Date		06-2021	06-2021	06-2021
Date of Initiation		24-06-2021	24-06-2021	24-06-2021
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted. Not valid.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. 00135/2021-DRAP (PS)/544 dated 10-02-2021 mentioning 200GM of Vonoprazan Fumarate attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.		

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm.
1.	1.3.4	Valid copy of DML and GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.6.5	• Name of the drug substance manufacturer mentioned in section 1.6.5 and that on GMP certificate are different from each other. Clarification shall be submitted. • Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
4.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of the drug substance from the drug substance manufacturer shall be submitted.	
6.	3.2.S.4.3	Analytical method verification protocol along with complete results of the analytical method verification shall be submitted.	
7.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned Assay of ≥ 99% while the drug product manufacturer has mentioned Assay limit of 98% - 102%. Clarification shall be submitted.	
8.	3.2.S.5	• COA and details of the reference standard used in the development studies shall be submitted. • For working standard firm has referred to 3.2.S.2.2 while no DMF is provided. Justification shall be submitted.	
9.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted.	

		Content uniformity test is not performed in the pharmaceutical equivalence studies. Justify. Values of f_2 in CDPs shall be submitted for all the mediums.	
10.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justify the variation of dissolution parameters i.e. rpm, dissolution medium and limits from that recommended by USFDA for the vonoprazan tablets.	
11.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method verification for the finished product shall be submitted.	
12.	3.2.P.5.4	Specification of the finished product has mentioned limits of weight variation test as 220mg ± 7.5% while the COA of the finished product has mentioned 178mg ± 7.5%. clarification shall be submitted.	
13.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.	
14.	3.2.P.8	• Stability summary sheets and stability data sheets are completely different with respect to batch number, batch size, manufacturing date, start date of stability studies etc. justification shall be submitted. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

Decision of 331st meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm.
1.	Valid copy of DML and GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	Firm has submitted copy of DML No. 000574 with renewal date from 20-05-2022. Copy of GMP certificate No. F.11-76/2022-DRAP-69 dated 10-06-2022 issued on the basis of inspection conducted on 30-03-2022.
2.	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-7/2004-Lic (Vol-I) dated 04-06-2022 mentioning Tablet (General) section.
3.	• Name of the drug substance manufacturer mentioned in section 1.6.5 and that on GMP certificate are different from each other. Clarification shall be submitted. • Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted. Firm has also submitted copy of License No. Yue20160016 for the drug substance manufacturer. *However, GMP certificate is invalid and the License number could not be verified from online data of NMPA website.*
4.	Specification of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.

5.	Analytical procedures of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
6.	Analytical method verification protocol along with complete results of the analytical method verification shall be submitted.	Submitted.
7.	COA of the drug substance from drug substance manufacturer has mentioned Assay of ≥ 99% while the drug product manufacturer has mentioned Assay limit of 98% - 102%. Clarification shall be submitted.	Firm has submitted that they mistakenly mentioned the assay limit of 98% - 102 instead of NLT 99.0%. they further submitted revised COA as per drug substance manufacturer.
8.	• COA and details of the reference standard used in the development studies shall be submitted. • For working standard firm has referred to 3.2.S.2.2 while no DMF is provided. Justification shall be submitted.	Firm has submitted COA of the reference standard.
9.	Justification for not performing CDP & PE against the innovator product shall be submitted. Content uniformity test is not performed in the pharmaceutical equivalence studies. Justify. Values of f_2 in CDPs shall be submitted for all the mediums.	Firm has submitted that due to unavailability of the innovator product in the market, they used brand leader available in local market in the CDP studies. Firm has submitted revised PE studies wherein they have added results of content uniformity test.
10.	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justify the variation of dissolution parameters i.e. rpm, dissolution medium and limits from that recommended by USFDA for the vonoprazan tablets.	Submitted. Firm has submitted revised dissolution specifications as per USFDA method for Vonoprazan tablets.
11.	Analytical method verification protocol along with complete results of the analytical method verification for the finished product shall be submitted.	Submitted.
12.	Specification of the finished product has mentioned limits of weight variation test as 220mg ± 7.5% while the COA of the finished product has mentioned 178mg ± 7.5%. clarification shall be submitted.	Firm has submitted revised COAs for all the three batches wherein they have changed weight variation specification from178mg ± 7.5% to 220mg ± 7.5% and the results are within the new limits.
13.	COA and details of the reference standard used in the development studies shall be submitted.	Submitted.
14.	• Stability summary sheets and stability data sheets are completely different with respect to batch number, batch size, manufacturing date, start date of stability studies etc. justification shall be submitted. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted.	Firm has submitted that by clerical mistake it happened. They further submitted corrected one. Firm has submitted that they have performed content uniformity test at initial stage and also submitted COAs wherein they have included the same. Firm has submitted that HPLC chromatograms does not contain wavelength rather it is retention time versus absorbance (peak height) moreover, in UV spectrum wavelength versus absorbance is usually measured. Submitted.

	• Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	irm has submitted that their product is approved in 331st meeting on form 5F. Submitted. Submitted.

Decision: Approved. Registration letter will be issued after submission of full fee i.e. 30,000/- for more typo errors and submission of valid GMP certificate/DML of the drug substance manufacturer issued by relevant/concerned regulatory authority.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

858.	**Name, address of Applicant / Marketing Authorization Holder**	**Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted inspection report of 2018. Not valid.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6133 dated 07-03-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 60062819 Dated 24/01/2022.
	The proposed proprietary name / brand name	**Wonowrd 20mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate 20mg
	Pharmacotherapeutic Group of (API)	Anti-ulcerative, Proton Pump Inhibitor.
	Pharmaceutical form of applied drug	Oral tablet.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	3 x 10's.

	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Takecab 20 mg Tablets by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Cindo 20mg tablets, Horizon Healthcare, Reg. No. 111619.
	Name and address of API manufacturer.	Xianqiang Pharmaceutical Pvt. Ltd., No. 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou city, Guangdong Province, China. Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (TAK09R210101, mfg. date 04-01-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. TAK09R150701, TAK09R150702 & TAK09R150703.
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the comparator product i.e. Vonozan 20mg tablets, B. No. 001FF9, mfg. date 05-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, weight variation, Disintegration, Dissolution & Assay). CDP has been performed against the same brand that is Vonozan 10mg tablets, B. No. 002FF9, mfg. date

		05-2021 manufactured by M/s Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API	Xianqiang Pharmaceutical Pvt. Ltd., No. 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou city, Guangdong Province, China.		
API Lot No.	VZ20190302.		
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	900 Tablets.	900 Tablets.	900 Tablets.
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	29-06-2021	29-06-2021	29-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. 00135/2021-DRAP (PS)/544 dated 10-02-2021 mentioning 200GM of Vonoprazan Fumarate attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm.

1.	1.3.4	Valid copy of DML and GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.6.5	• Name of the drug substance manufacturer mentioned in section 1.6.5 and that on GMP certificate are different from each other. Clarification shall be submitted. • Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
4.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of the drug substance from the drug substance manufacturer shall be submitted.	
6.	3.2.S.4.3	Analytical method verification protocol along with complete results of the analytical method verification shall be submitted.	
7.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned Assay of ≥ 99% while the drug product manufacturer has mentioned Assay limit of 98% - 102%. Clarification shall be submitted.	
8.	3.2.S.5	• COA and details of the reference standard used in the development studies shall be submitted. • For working standard firm has referred to 3.2.S.2.2 while no DMF is provided. Justification shall be submitted.	
9.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted. Content uniformity test is not performed in the pharmaceutical equivalence studies. Justify. Values of f_2 in CDPs shall be submitted for all the mediums.	
10.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justify the variation of dissolution parameters i.e. rpm, dissolution medium and limits from that recommended by USFDA for the vonoprazan tablets.	
11.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method verification for the finished product shall be submitted.	
12.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.	
13.	3.2.P.8	• Stability summary sheets and stability data sheets are completely different with respect to batch number, batch size, manufacturing date, start date of stability studies etc. justification shall be submitted. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

Decision of 331st meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm.
1.	Valid copy of DML and GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	Firm has submitted copy of DML No. 000574 with renewal date from 20-05-2022. Copy of GMP certificate No. F.11-76/2022-DRAP-69 dated 10-06-2022 issued on the basis of inspection conducted on 30-03-2022.
2.	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-7/2004-Lic (Vol-I) dated 04-06-2022 mentioning Tablet (General) section.
3.	• Name of the drug substance manufacturer mentioned in section 1.6.5 and that on GMP certificate are different from each other. Clarification shall be submitted. • Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. GD20150397 dated 07-09-2015 valid till 06-09-2020 is submitted. Firm has also submitted copy of License No. Yue20160016 for the drug substance manufacturer. *However, GMP certificate is invalid and the License number could not be verified from online data of NMPA website.*
4.	Specification of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
5.	Analytical procedures of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
6.	Analytical method verification protocol along with complete results of the analytical method verification shall be submitted.	Submitted.
7.	COA of the drug substance from drug substance manufacturer has mentioned Assay of ≥ 99% while the drug product manufacturer has mentioned Assay limit of 98% - 102%. Clarification shall be submitted.	Firm has submitted that they mistakenly mentioned the assay limit of 98% - 102 instead of NLT 99.0%. they further submitted revised COA as per drug substance manufacturer.
8.	• COA and details of the reference standard used in the development studies shall be submitted. • For working standard firm has referred to 3.2.S.2.2 while no DMF is provided. Justification shall be submitted.	Firm has submitted COA of the reference standard.
9.	Justification for not performing CDP & PE against the innovator product shall be submitted. Content uniformity test is not performed in the pharmaceutical equivalence studies. Justify. Values of f_2 in CDPs shall be submitted for all the mediums.	Firm has submitted that due to unavailability of the innovator product in the market, they used brand leader available in local market in the CDP studies. Firm has submitted revised PE studies wherein they have added results of content uniformity test.
10.	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justify the variation of dissolution parameters i.e. rpm, dissolution medium and limits from that recommended by USFDA for the vonoprazan tablets.	Submitted. Firm has submitted revised dissolution specifications as per USFDA method for Vonoprazan tablets.
11.	Analytical method verification protocol along with complete results of the analytical method verification for the finished product shall be submitted.	Submitted. *However, firm has once again submitted method verification studies for the drug substance instead of the drug product.*

12.	COA and details of the reference standard used in the development studies shall be submitted.	Submitted.
13.	• Stability summary sheets and stability data sheets are completely different with respect to batch number, batch size, manufacturing date, start date of stability studies etc. justification shall be submitted. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted that by clerical mistake it happened. They further submitted corrected one. Firm has submitted that they have performed content uniformity test at initial stage and also submitted COAs wherein they have included the same. Firm has submitted that HPLC chromatograms does not contain wavelength rather it is retention time versus absorbance (peak height) moreover, in UV spectrum wavelength versus absorbance is usually measured. Submitted. Firm has submitted that their product is approved in 331st meeting on form 5F. Submitted. Submitted.

Decision: Approved. Registration letter will be issued after submission of full fee i.e. 30,000/- for more typo errors and submission of valid GMP certificate/DML of the drug substance manufacturer issued by relevant/concerned regulatory authority.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

859.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23986, dated 02/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 401648091719 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Levocin 250mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin hemihydrate eq. to levofloxacin ..… 250mg
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levofloxacin 250 mg film-coated tablets, MHRA Approved.
	For generic drugs (me-too status)	Lovenox Tablets 250mg, Don Valley, Reg. No. 069370.
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. DC-004-2007009, Mfg. date 11-07-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: DC-004-1512001, DC-004-1512002 & DC-004-1512003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container

		closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Levaquin 250mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Levaquin 250mg tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	14-12-2021	15-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. AH20150265) dated 23-12-2020 issued by China Foods & drugs Administration. The certificate specifies that the firm complies with the requirements of Chinese Good Manufacturing Practices for pharmaceutical products. Valid till 22-12-2025. Online verification confirms the validity till 22-12-2020 and the status is "Expired".
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TSN0882021 dated 26-10-2021 mentioning 4kg of levofloxacin hemihydrate USP with B. No. DC-004-2007009, Mfg. date 11-07-2020 attested Assistant Director (I&E) DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 09-11-2021.

10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.6.5	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	
4.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.		Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	
7.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	Firm has submitted copy of License No. Zhejiang 20000312 issued by Zhejiang provincial Drug Administration in the name of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., dated 19-07-2022 valid till 07-10-2024.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMRs for all the three trial batches.
5.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	Submitted.
7.	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	*Not submitted.* Firm has submitted following details; Levaquin 250mg tablets, B. No. K44638 & Exp. date of 10-2024. Firm has submitted revised results for CDP and further submitted that during compilation of the data results of 250mg were replaced with 500mg. Newly/revised results have different values than the initially submitted ones.
8.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. DC-004-2007009. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which

	• • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

860.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23987, dated 02/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 17271517116 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Levocin 500mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin hemihydrate eq. to levofloxacin ..… 500mg
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levofloxacin 500 mg film-coated tablets, MHRA Approved.
	For generic drugs (me-too status)	Lovenox Tablets 50mg, M/s Don Valley, Reg. No. 069371.

	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. DC-004-2007009, Mfg. date 11-07-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DC-004-1512001, DC-004-1512002 & DC-004-1512003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Levaquin 500mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Levaquin 250mg tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
API Lot No.	Not submitted.
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	14-12-2021	15-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. AH20150265) dated 23-12-2020 issued by China Foods & drugs Administration. The certificate specifies that the firm complies with the requirements of Chinese Good Manufacturing Practices for pharmaceutical products. Valid till 22-12-2025. Online verification confirms the validity till 22-12-2020 and the status is "Expired".
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TSN0882021 dated 26-10-2021 mentioning 4kg of levofloxacin hemihydrate USP with B. No. DC-004-2007009, Mfg. date 11-07-2020 attested Assistant Director (I&E) DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 09-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	

3.	1.6.5	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	
4.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.		Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	
7.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by	Firm has submitted copy of License No. Zhejiang 20000312 issued by Zhejiang provincial Drug Administration in the name of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., dated 19-07-2022 valid till 07-10-2024.

	relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMRs for all the three trial batches.
5.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	Submitted.
7.	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	Firm has submitted following details; Levaquin 500mg tablets, B. No. M9531 & Exp. date of 03-2024. Firm has submitted that during compilation of the data results of 250mg were replaced with 500mg. Newly/revised results for 250 mg are different from the initially submitted ones.
8.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. DC-004-2007009. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

861.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26382, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 60305514498 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Itrazole 100mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Itraconazole as IR pellets ……100mg
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	4's or As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Sporanox 100mg capsule, MHRA approved.
	For generic drugs (me-too status)	Rolac 100mg Capsules, Sami Pharmaceuticals, Reg. No. 024491.
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt.) Ltd., 10th Km Faisalabad Road, Bikhi, District Sheikhupura – Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. ITC-22-001, Mfg. date 10-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Batches: ITC-22-IR-051, ITC-22-IR-053 & ITC-22-IR-054.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Sporanox Capsule by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Sporanox Capsule in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F_2 values calculated are in acceptable renge.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Surge Laboratories (Pvt.) Ltd., 10th Km Faisalabad Road, Bikhi, District Sheikhupura – Pakistan.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	White to off-white spherical IR pellets filled in hard gelatin capsule, blistered in Alu-Alu and further packed in bleach card units.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	15/01/2022	16/01/2022	17/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 182/2019-DRAP (AD-823166-158) dated 04-07-2019 issued on the basis of inspection conducted on 03-07-2019 is submitted by the firm.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	3.2.S.7	Stability studies of the drug substance from drug substance manufacturer shall be submitted.	
4.	2.3	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted.	
6.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.

	No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. 189/2022-DRAP (AD-9978029213) dated 20-10-2022 issued on the basis of inspection conducted on 25-08-2022 is submitted by the firm.
3.	Stability studies of the drug substance from drug substance manufacturer shall be submitted.	Firm has submitted stability studies of three batches for the drug substance.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMRs.
5.	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted.	Firm has submitted that PE and CDP were performed against Sporanox capsules, manufactured by Jannsen pharmaceuticals. *No details are provided by the firm.*
6.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. ITC-22-001. Firm has submitted that drug substance was purchased locally, therefore no approval from DRAP is required. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

862.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Sterile liquid injection ampoule SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.25885, dated 26/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 021933578 dated: 15/09/2023.
	The proposed proprietary name / brand name	**Ketrol 10mg/ml injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine……10mg
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drug (NSAID).
	Pharmaceutical form of applied drug	Solution for injection.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1ml x 5's OR As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ketorolac Trometamol 10 mg/ml solution for injection, MHRA approved.
	For generic drugs (me-too status)	Toradol 10mg/ml (IV/IM), Martin Dow, Reg. No. 014908.
	Name and address of API manufacturer.	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. KM-0302021, Mfg. date 03-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months. Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: KM-1102215, KM-1102315 & KM-1102415.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Toradol injection by performing quality tests identification, volume variation, pH, Particulate matter, Assay, Bacterial endotoxin and Sterility.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Type I clear glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	K004	K005	K006
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	16/01/2022	17/01/2022	18/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License (No. 106490/TS/2023) dated 11-03-2023 issued by Drugs Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 09-03-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TWE/CIB.I/20-21 dated 09-11-2021 mentioning 0.2Kg of Ketorolac Tromethamine with B. No. KM-0302021, manufacturing date of 03-2021 attested by Assistant Director, I&E, DRAP Karachi dated 23-11-2021. Firm has also submitted attested copy of Form 6.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	2.3.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	3.2.P.1.1	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	
4.	3.2.P.2.2	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	
5.	3.2.P.2.6	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	
6.	3.2.P.3.3	Justification shall be submitted for terminal sterilization of the applied formulation.	
7.	3.2.P.5.2	Analytical method for assay test has mentioned that transfer 0.83ml of solution which is equivalent to 25mg of ketorolac Tromethamine. Justification shall be submitted that how 0.83 ml will contain 25mg of ketorolac Tromethamine while 1ml of ampoule contains 10mg.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted corrected/revised table for literature references. *However, applicable fee is not submitted.* Firm has submitted copies of executed BMR's.
3.	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	Firm has submitted that the qualitative composition of the applied product was approximately same as that of the innovator product "Toradol injection". The propylene glycol was used to dissolve the ketorolac Tromethamine. FDA defines the use of hydrochloric acid or Sodium hydroxide to adjust the pH of the solution to a limit of 6.9 – 7.9. In our formulation the pH was adjusted with sodium hydroxide.
4.	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	Firm has submitted that Toradol injection, B. No. C1395, Exp. date 03-2023 manufactured by M/s Martin Dow, Marker Pakistan was used in PE studies.
5.	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	The composition of Toradol injection was followed while the formulation was developed. The qualitative composition of the applied product was approximately same as that of the innovator product "Toradol injection". The propylene glycol was used to dissolve the ketorolac Tromethamine. FDA defines the use of hydrochloric acid or Sodium hydroxide to adjust the pH of the solution to a limit of 6.9 – 7.9. In our formulation the pH was adjusted with sodium hydroxide. Hydrochloric acid was not required as pH was adjusted with sodium hydroxide.
6.	Justification shall be submitted for terminal sterilization of the applied formulation.	Firm has submitted that as per WHO guidelines (Annex 6 WHO Good manufacturing practices for sterile pharmaceutical products) products intended to be sterile should be terminally sterilized by heat in their final containers. Terminal

		sterilization is done to assure the product is sterile and free from pyrogen.
7.	Analytical method for assay test has mentioned that transfer 0.83ml of solution which is equivalent to 25mg of ketorolac Tromethamine. Justification shall be submitted that how 0.83 ml will contain 25mg of ketorolac Tromethamine while 1ml of ampoule contains 10mg.	Firm has submitted that it was a typo error. This method was for 30mg/ml injection instead of 10mg/ml. They submitted revised method.
8.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. KM0302021. Firm has submitted that drug substance was purchased locally, therefore no approval from DRAP is required. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

863.		
	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Sterile liquid injection ampoule SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.25886, dated 26/10/2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 3185831822 dated: 15/09/2023.
	The proposed proprietary name / brand name	**Ketrol 30mg/ml injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine……30mg
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drug (NSAID).
	Pharmaceutical form of applied drug	Solution for injection.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1ml x 5's OR As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ketorolac Trometamol 30 mg/ml solution for injection, MHRA approved.
	For generic drugs (me-too status)	Racmic Injection, Neutro Pharma, Reg. No. 068025.
	Name and address of API manufacturer.	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. KM-0302021, Mfg. date 03-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months. Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: KM-1102215, KM-1102315 & KM-1102415.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and	Pharmaceutical Equivalence is established against the

	comparative dissolution profile	brand that is Toradol injection by performing quality tests identification, volume variation, pH, Particulate matter, Assay, Bacterial endotoxin and Sterility.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Type I clear glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	K001	K002	K003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	16/01/2022	17/01/2022	18/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License (No. 106490/TS/2023) dated 11-03-2023 issued by Drugs Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 09-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TWE/CIB.I/20-21 dated 09-11-2021 mentioning 0.2Kg of Ketorolac Tromethamine with B. No. KM-0302021, manufacturing date of 03-2021 attested by Assistant Director, I&E, DRAP Karachi dated 23-11-2021. Firm has also submitted attested copy of Form 6.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring	Submitted

	of stability chambers (real time and accelerated)	

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	2.3.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	3.2.P.1.1	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	
4.	3.2.P.2.2	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	
5.	3.2.P.2.6	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	
6.	3.2.P.3.3	Justification shall be submitted for terminal sterilization of the applied formulation.	
7.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug	Firm has submitted corrected/revised table for literature references. However, applicable fee is not submitted. Firm has submitted copies of executed BMR's.

	product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	Firm has submitted that the qualitative composition of the applied product was approximately same as that of the innovator product "Toradol injection". The propylene glycol was used to dissolve the ketorolac Tromethamine. FDA defines the use of hydrochloric acid or Sodium hydroxide to adjust the pH of the solution to a limit of 6.9 – 7.9. In our formulation the pH was adjusted with sodium hydroxide.
4.	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	Firm has submitted that Toradol injection, B. No. manufactured by M/s Martin Dow, Marker Pakistan was used in PE studies.
5.	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	The composition of Toradol injection was followed while the formulation was developed. The qualitative composition of the applied product was approximately same as that of the innovator product "Toradol injection". The propylene glycol was used to dissolve the ketorolac Tromethamine. FDA defines the use of hydrochloric acid or Sodium hydroxide to adjust the pH of the solution to a limit of 6.9 – 7.9. In our formulation the pH was adjusted with sodium hydroxide. Hydrochloric acid was not required as pH was adjusted with sodium hydroxide.
6.	Justification shall be submitted for terminal sterilization of the applied formulation.	Firm has submitted that as per WHO guidelines (Annex 6 WHO Good manufacturing practices for sterile pharmaceutical products) products intended to be sterile should be terminally sterilized by heat in their final containers. Terminal sterilization is done to assure the product is sterile and free from pyrogen. *Innovator product has no terminal sterilization.*
7.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. KM0302021. Firm has submitted that drug substance was purchased locally, therefore no approval from DRAP is required. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
864.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.17331, dated 11/07/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0843732876 dated: 15/08/2022.
	The proposed proprietary name / brand name	**Asthma-F Tablet 10mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium……10mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists.
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Singulair 10mg tablets, USFDA approved.
	For generic drugs (me-too status)	Montair 10mg tablets, CCL Pharmaceuticals, Reg. No. 029952.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Masukhana, Parwanoo Distt. Solan [H.P.] India. Copy of GMP certificate No. HFW-H (Drugs) 93/91 issued by State Drugs Controller in the name of M/s Morepen Laboratories Limited, valid till 31-12-2026 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. MS/2107003, Mfg. date 07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C / 65% RH for 24 months Accelerated: 40°C / 75% RH for 6 months Batches: MTN14-8015, MTN14-9001 & MTN14-9036
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Singulair tablets, B. No. 112472, Exp. date 06-2024 manufactured by M/s Merck Research Laboratories by performing quality tests content uniformity, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Singulair tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Morepen Laboratories Limited, Village Masukhana, Parwanoo Distt. Solan [H.P.] India.		
API Lot No.	MS/2107003.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	AF-001	AF-002	AF-003
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets

Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	01/2022	01/2022	01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HFW-H (Drugs) 93/91 issued by State Drugs Controller in the name of M/s Morepen Laboratories Limited, valid till 31-12-2026 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a clearance certificate. However, it is not in readable form.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Justification shall be submitted regarding the analytical method from drug substance manufacturer as all the parameters including flow rate, injection volume, wave length diluent, standard preparation, sample preparation etc. are completely different from USP monograph.	
6.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.P.2.2	Calculations and values of F_2 for all the three mediums shall be submitted.	
8.	3.2.P.8	Clear and readable documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMR's for the trial batches.
4.	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
5.	Justification shall be submitted regarding the analytical method from drug substance manufacturer as all the parameters including flow rate, injection volume, wave length diluent, standard preparation, sample preparation etc. are completely different from USP monograph.	Firm has submitted revised analytical method from drug substance manufacturer as per USP method wherein the mentioned parameters are as per USP.
6.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	Calculations and values of F_2 for all the three mediums shall be submitted.	Firm has submitted F_2 values for all the three mediums and these values are in acceptable ranges.
8.	Clear and readable documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted copy of commercial invoice No. EXP/090018-21 dated 25-10-2021 mentioning 200gm of Montelukast sodium, B. No. MS/2017003 attested by Assistant Director, DRAP, Karachi dated 18-11-2021. Firm has also submitted attested copy of Form 6. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

865.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18307, dated 20/07/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 773720227775 dated: 04/07/2023.
	The proposed proprietary name / brand name	**Newgab capsule 50mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin……50mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 50mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 50mg Capsule, Mediate Pharmaceutical, Reg. No. 074971.
	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 50 mg with batch No. LR12547, expiry date 11-2024 manufactured by M/s Pfizer by performing quality tests average weight, content uniformity, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 50 mg with batch No. LC1254, expiry date 11-2023 manufactured by M/s Pfizer in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both reference and applied formulations have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.		
API Lot No.	PG213041.		
Description of Pack (Container closure system)	1 x 7's capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	NG-001	AF-002	
Batch Size	5000 Capsules	5000 Capsules	
Manufacturing Date	05/2022	05/2022	
Date of Initiation	11/05/2022	11/05/2022	
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.5.15 to 1.5.20	All commitments shall be submitted.	
4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	
7.	3.2.P.2.2	Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	
8.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

Decision of 333rd meeting of Registration board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	All commitments shall be submitted.	Submitted.
4.	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted corrected/revised table for literature references. *However, applicable fee is not submitted.* Firm has submitted copies of executed BMR's.
5.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	Firm has submitted real time stability study data for the same batches i.e. PG120001, PG120002 & PG120003 as per zone Iva.
7.	Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	Firm has submitted that PE and CDP studies are performed against Lyrica 50mg, B. No. LR12547, Exp. date 11-2024 manufactured by M/s Pfizer.
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

866.		
	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27249, dated 20/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 5050548001 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Newgab 75mg capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin……75mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 75mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 75mg Capsule, Mediate Pharmaceutical, Reg. No. 074977.
	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 75 mg with manufactured by M/s Pfizer by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 75 mg in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both reference and applied formulations and values of F_2 are in acceptable range.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.		
API Lot No.	PG213041.		
Description of Pack (Container closure system)	Capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	20/12/2021	21/12/2021	22/12/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.5.15 to 1.5.20	All commitments shall be submitted.	
4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	
7.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	
8.	3.2.P.5.1	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.	
9.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

		• Injection volume in the submitted chromatograms with respect to the official monograph shall be justified.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm;

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	All commitments shall be submitted.	Submitted.
4.	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted corrected/revised table for literature references. *However, applicable fee is not submitted.* Firm has submitted copies of executed BMR's.
5.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	Firm has submitted real time stability study data for the same batches i.e. PG120001, PG120002 & PG120003 as per zone Iva.
7.	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	Firm has submitted that PE and CDP studies are performed against Lyrica 75mg, B. No. LR1185, Exp. date 09-2024 manufactured by M/s Pfizer.
8.	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.	Firm has submitted that their specifications NLT 80% (Q) in 15 are within the limit of BP i.e. 30 minutes.
9.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. PG213041. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

867.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27250, dated 20/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 566988064 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Newgab 100mg capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin……100mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 100mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 100mg Capsule, Mediate Pharmaceutical, Reg. No. 074972.

	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 75 mg with manufactured by M/s Pfizer by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 75 mg in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both reference and applied formulations and values of F_2 are in acceptable range.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.

API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	20/12/2021	21/12/2021	22/12/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.5.15 to 1.5.20	All commitments shall be submitted.	

4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	
7.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	
8.	3.2.P.5.1	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.	
9.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Injection volume in the submitted chromatograms with respect to the official monograph shall be justified.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	All commitments shall be submitted.	Submitted.
4.	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted corrected/revised table for literature references. ***However, applicable fee is not submitted.*** Firm has submitted copies of executed BMR's.
5.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Clear and readable copies of real time stability studies of the drug substance for	Firm has submitted real time stability study data for the same batches i.e. PG120001, PG120002 & PG120003 as per zone Iva.

	three batches as per zone Iva shall be submitted.	
7.	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	Firm has submitted that PE and CDP studies are performed against Lyrica 100mg, B. No. LR0925, Exp. date 07-2024 manufactured by M/s Pfizer.
8.	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.	Firm has submitted that their specifications NLT 80% (Q) in 15 are within the limit of BP i.e. 30 minutes.
9.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. PG213041. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

868.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24323, dated 04/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 228659180716 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Ternafine 250mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Terbinafine as Hydrochloride ……..…… 250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	Oral, Uncoated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	10's or As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lamisil 250mg tablet, TGA Australia Approved.
	For generic drugs (me-too status)	Brandit 250mg tablet, High-Q Pharmaceutical, Reg. No. 090823.
	Name and address of API manufacturer.	M/s Saptagir Laboratories (Pvt.) Ltd., Sy. No. Parts of 27, 46 and 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. TER04422, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: TH0131216, TH0141216 & TH0151216.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product,

		specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Lamisil 250mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lamisil 250mg tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Saptagir Laboratories (Pvt.) Ltd., Sy. No. Parts of 27, 46 and 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak District, Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	TR004	TR005	TR006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	28-11-2021	29-11-2021	30-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 82079/TS/2022) dated 22-09-2022 issued by Drug Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 22-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021 specifying 2.0Kg of Terbinafine Hydrochloride attested by Assistant Director (I&E) DRAP, Karachi dated 22-11-2021. Firm has also submitted copy of form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 22-11-2021.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.5	COA and details of the working standard used in the trial batches shall be submitted.	
5.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator pack with visible details shall also be submitted.	
6.	3.2.P.6	COA and details of the working standard used in the trial batches shall be submitted.	
7.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Valid copy of GMP certificate for the drug substance manufacturer issued by	Firm has submitted copy of GMP Certificate (No. 82079/TS/2023) dated 26-09-2023 issued by

	relevant/concerned authority shall be submitted.	Drug Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 26-09-2024.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMR's.
4.	COA and details of the working standard used in the trial batches shall be submitted.	Submitted.
5.	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator pack with visible details shall also be submitted.	Firm has submitted that CDP and PE studies are performed against Lamisil 250mg Tablets, B. No. BAA079, Exp. date 03-2023 manufactured by M/s Pfizer.
6.	COA and details of the working standard used in the trial batches shall be submitted.	Submitted.
7.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. TER04422. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

869.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26385, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 8729259911 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 120mg/5ml Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of suspension contains: Paracetamol……120mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.
	Pharmaceutical form of applied drug	Oral suspension.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Calpol Sugar Free Infant Suspension MHRA approved.
	For generic drugs (me-too status)	Paracetamol suspension, Ferozsons laboratories, Reg. No. 001517.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol suspension with batch No. 321062, expiry date 08-2022 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Amber glass bottles 0f 60ml closed with white PP child proof screw caps.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.

		Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	
5.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	

Decision of 333rd meeting of Registration board.: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for	Firm has submitted copies of executed BMR's.

	which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	Firm has submitted COA's of the drug substance from both drug substance manufacturer and finished product manufacturer mentioning batch no. 202109103A, mfg. date 23-09-2021.
5.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. 202109103A. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated. Firm has submitted that according to USP, minor parameters can be adjusted according to the system requirement. They further submitted that all the parameters were followed as per USP, however, injection volume was adjusted as the system suitability results with 20µl injection were more precise and accurate. All the other major parameters i.e. flow rate, concentration of standard and sample, column diameter, length and packing, temperature, detection wavelength mobile phase and diluent are same as describe in USP.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

870.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26386, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 244818459 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 250mg/5ml Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of suspension contains: Paracetamol……250mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.
	Pharmaceutical form of applied drug	Oral suspension.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Calpol Six Plus Suspension, MHRA approved.
	For generic drugs (me-too status)	Mismol plus suspension, Mission pharmaceuticals, Reg. No. 080313.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product,

		specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol six plus suspension with batch No. 48693, expiry date 08-2022 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Amber glass bottles 0f 60ml closed with white PP child proof screw caps.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T004	T005	T006
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	
5.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMR's.
4.	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	Firm has submitted COA's of the drug substance from both drug substance manufacturer and finished product manufacturer mentioning batch no. 202109103A, mfg. date 23-09-2021.

5.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. 202109103A. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated. Firm has submitted that according to USP, minor parameters can be adjusted according to the system requirement. They further submitted that all the parameters were followed as per USP, however, injection volume was adjusted as the system suitability results with 20µl injection were more precise and accurate. All the other major parameters i.e. flow rate, concentration of standard and sample, column diameter, length and packing, temperature, detection wavelength mobile phase and diluent are same as describe in USP.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

871.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26384, dated 01/11/2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 34443282668 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 80mg/0.8ml infant drops.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8ml (one calibrated dropper) of suspension contains: Paracetamol……80mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.
	Pharmaceutical form of applied drug	Oral Drops.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	PANADOL CHILDREN 1 MONTH - 1 YEAR paracetamol 100 mg/mL oral liquid bottle, TGA approved.
	For generic drugs (me-too status)	Munapol Infant drops, Munawar Pharma, Reg. No. 067775.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Panadol infants drops by GSK with batch No. M35K, expiry date 11-2023 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Amber glass bottles of 30ml packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T007	T008	T009
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring	Submitted

	of stability chambers (real time and accelerated)	

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	
5.		• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	Firm has submitted that it is a typo mistake and address is Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi. Also the fee challan has been generated from the portal of M/s Fortune Pharmaceuticals which could be verified online.
2.	Proposed pack size for the applied formulation shall be mentioned.	As per SRO/DPC.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Firm has submitted copies of executed BMR's.
4.	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	Firm has submitted COA's of the drug substance from both drug substance manufacturer and finished product manufacturer mentioning batch no. 202109103A, mfg. date 23-09-2021.
5.	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted.	Firm has submitted revised stability data sheets as per decision of Registration Board with inclusion of API lot No. I.e. 202109103A. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. Furthermore, the wavelength is mentioned in the standard analytical procedure. Firm has submitted that chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is 21CFR compliant but yet not activated. Firm has submitted that according to USP, minor parameters can be adjusted according to the system requirement. They further submitted that all the parameters were followed as per USP, however, injection volume was adjusted as the system suitability results with 20µl injection were more precise and accurate. All the other major parameters i.e. flow rate, concentration of standard and sample, column diameter, length and packing, temperature, detection wavelength mobile phase and diluent are same as describe in USP.

Decision: Approved. Registration letter will be issued after submission of an undertaking regarding the fee challan that it will not be used in any other application/purpose.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

872.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Name, address of Manufacturing site.	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 605; dated 06/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.16403533322 dated 14/07/2022.
	The proposed proprietary name / brand name	Montigen 4 mg Sachet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains; Montelukast as sodium …….. 4 mg

	Pharmaceutical form of applied drug	Oral Granules in sachet.
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR® (montelukast sodium) oral granules, USFDA Approved.
	For generic drugs (me-too status)	Montekast Sachet 4mg, Legacy Pharmaceuticals, Reg. No. 049906
	GMP status of the Finished product manufacturer	Not provided.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	M/s Dhanuka Laboratory Ltd., Plot No., SP4-4 Industrial Area Keshwana Rajput Kotputli Shahpura, Dist. Jaipur Rajasthan, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Montelukast Sodium is present in USP. Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis (MTS/1907004, mfg. date 07-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: (MLS-F#009/15, MLS-F#010/15 & MLS-F#011/15)
	Module-III (Drug Product):	Official monograph for Montelukast sodium oral granules is present in USP. Firm has submitted detail of the drug product regarding its description and composition, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator that is Singular 4mg Sachet, batch No. 21A601

		of Merck Research Laboratories by performing quality tests (Average weight, Dissolution, Assay, Content Uniformity). Comparative Dissolution is also performed against the same brand that is Singular 4mg Sachet by Merk reasarch laboratories in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Dhanuka Laboratory Ltd., Plot No., SP4-4 Industrial Area Keshwana Rajput Kotputli Shahpura, Dist. Jaipur Rajasthan, India.		
API Lot No.	MTS-1907004.		
Description of Pack (Container closure system)	Montigen is filled in sealed printed foil sachet 14 sachets are pack in unit carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-002	
Batch Size	4000 Sachet	4000 Sachet	
Manufacturing Date	04-2022	04-2022	
Date of Initiation	25-04-2022	25-04-2022	
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. SOK/EXP1920/0059 dated 19-11-2019 mentioning 5kg of Montelukast sodium USP, Batch No. MTS/1907004, mfg. date 07-2019 attested bi Assistant Director, I&E, DRAP, Islamabad. Invoice has mentioned Seraph pharmaceuticals as importer of the material.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation
1.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.
2.	1.3.5	Evidence of section approval letter of Biogen Life Sciences shall be submitted.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.
4.	1.6.5	Valid copy of GMP certificate of the Drug Substance manufacturer shall be submitted.
5.	2.3.R	• Table for literature references has not mentioned status of drug substance in all pharmacopoeias i.e.JP. Revised table for literature references with applicable fee shall be submitted.
6.	3.2.S.4.1	Specification of drug substance by drug substance manufacturer shall be submitted.
7.	3.2.S.4.2	Analytical procedures in USP has mentioned up to 16 minutes' time for assay of drug substance and in enantiomeric purity while the analytical procedure provided by the drug substance manufacturer has mentioned up to 25 minutes. Clarification shall be submitted.
8.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.
9.	3.2.S.5	Details and COA of the working standard used in the development of trial batches shall be submitted.
10.	3.2.P.2.2	• Justification shall be submitted for not performing identification test Pharmaceutical Equivalence. • Tabulated CDP results with all the time points in different medias shall be submitted. • Justification shall be submitted for the provided graphical results of CDP as it has mentioned some other brand names. • Raw data sheets for the CDP results shall be submitted.
11.	3.2.P.5.1	Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. Clarification shall be submitted.
12.	3.2.P.5.3	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.
13.	3.2.P.8	• Raw data sheets for both the assay test and dissolution test at each time point with chromatograms shall be submitted. Furthermore, each time point raw data sheets shall be accompanied with calculation formula. • Justification shall be submitted regarding the submitted chromatograms as it does not mention wave length of detector. • Justification shall be submitted regarding submitted chromatograms as it also does not reflect the resolution factor as required by the official monograph. • Complete six-month stability data shall be submitted. • Justification for manufacturing only two batches shall be submitted.
14.		• Clear and readable copy of the clearance certificate for import of raw material shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

		• Log of HPLC run showing change in concentration of mobile phase is required. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.
15.	3.2.R	Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied product along with copies of executed BMRs shall be submitted.

Decision of 326th meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.	Firm has submitted copy of DML No. 000911 in the name of M/s Biogen Pharmaceuticals w.e.f. 13-02-2020 and also provided change of title vide letter No. F. 1-2/2019-Lic. Dated 18-03-2021 from M/s Biogen Pharmaceuticals to M/s Biogen Life Sciences. Firm has submitted copy of inspection report conducted for verification of GMP compliance dated 01-06-2023 wherein panel in the conclusion has mentioned that M/s Biogen life sciences can be considered to have acceptable compliance level of GMP subject to the condition that firm must install FTIR within one month and same be verified by the area FID.
2.	1.3.5	Evidence of section approval letter of Biogen Life Sciences shall be submitted.	Firm has submitted copy of section approval vide letter No. F. 1-2/2019-Lic. Dated 14-02-2020 wherein M/s Biogen pharmaceuticals have Sachet (general) section.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	14's.
4.	1.6.5	Valid copy of GMP certificate of the Drug Substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. DC/A-2/ WHO-GMP/2022/77 dated 27-01-2022 issued by Drugs Control Organization Jaipur (Rajasthan) valid for three years.
5.	2.3.R	Table for literature references has not mentioned status of drug substance in all pharmacopoeias i.e.JP. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted revised table for literature references with correct information regarding both drug substances and drug product without any fee.
6.	3.2.S.4.1	Specification of drug substance by drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.2	Analytical procedures in USP has mentioned up to 16 minutes' time for assay of drug substance and in enantiomeric purity while the analytical procedure provided by the drug substance manufacturer has mentioned	Firm has submitted that they drafted raw material test method for montelukast sodium according to USP monograph and raw material test was performed according to draft test method that complies USP parameters.

		up to 25 minutes. Clarification shall be submitted.	
8.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted analytical method verification studies for the drug substance. *However, submitted verification studies are from Biogen pharmaceuticals instead of Biogen life sciences.*
9.	3.2.S.5	Details and COA of the working standard used in the development of trial batches shall be submitted.	Firm has submitted COA of the working standard with working standard number WS/10/003.
10.	3.2.P.2.2	• Justification shall be submitted for not performing identification test Pharmaceutical Equivalence. • Tabulated CDP results with all the time points in different medias shall be submitted. • Justification shall be submitted for the provided graphical results of CDP as it has mentioned some other brand names. • Raw data sheets for the CDP results shall be submitted.	Firm has submitted that test method includes 2 tests for identification i.e. UV and HPLC. They used HPLC method instead of UV and that complies during assay of the test and reference product. Submitted. Firm has submitted that it was a typographic error and they corrected it in updated CDP results. *Not submitted.*
11.	3.2.P.5.1	Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. Clarification shall be submitted.	Firm has submitted that there was a drafting error in mentioning the salt form of WS/RS used for raw material and trial analysis. Working standard used during all trial analysis was montelukast dicyclohexylamine and same could be verified from COA of the working standard. *Firm was asked that Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. However, they didn't respond to the same.*
12.	3.2.P.5.3	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Firm has submitted analytical method verification studies for the drug substance. *However, submitted verification studies are from Biogen pharmaceuticals instead of Biogen life sciences.*
13.	3.2.P.8	• Raw data sheets for both the assay test and dissolution test at each time point with chromatograms shall be submitted. Furthermore, each time point raw data sheets shall be accompanied with calculation formula. • Justification shall be submitted regarding the submitted chromatograms as it does not mention wave length of detector.	Submitted. Firm has submitted that trial analysis was performed on HPLC. During the creation of method, all the method inputs i.e. wavelength, mobile phase channels & their ratio, injection volume and run time are added.

		• Justification shall be submitted regarding submitted chromatograms as it also does not reflect the resolution factor as required by the official monograph. • Complete six-month stability data shall be submitted. • Justification for manufacturing only two batches shall be submitted.	Firm has submitted that chromatograms have been generated on default report template wherein option for reporting wavelength was not enabled, however, from future onwards all data shall be generated according to the said requirements. Submitted. Firm has submitted that guidance document for submission of application on Form 5F for registration of pharmaceutical products for human use suggests that 02 batches can be taken if/for the oral suspension if their batch size is 2000 units.
14.		• Clear and readable copy of the clearance certificate for import of raw material shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Log of HPLC run showing change in concentration of mobile phase is required. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted copy of commercial invoice No. SOK/EXP1920/0059 dated 19-11-2019 mentioning 5kg of Montelukast sodium USP, Batch No. MTS/1907004, mfg. date 07-2019 attested bi Assistant Director, I&E, DRAP, Islamabad. Invoice has mentioned Seraph pharmaceuticals as importer of the material. Firm has submitted that ADC clearance certificate of M/s Seraph pharma is submitted which is our sister concern. *However, as per decision of the Registration Board regarding the Borrowing of API's for performing Product Development, R&D & Stability testing, no receiving is submitted by the firm for borrowing of API.* *Not submitted.* Submitted.
15.	3.2.R	Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied product along with copies of executed BMRs shall be submitted.	***Not submitted.***

Decision of 331st meeting of Registration Board:

Deferred for following;

- Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.
- Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.
- Raw data sheets for the CDP results shall be submitted.
- Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. Clarification shall be submitted.

- Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.
- Documents for procurement of the drug substance attested by DRAP shall be submitted.
- Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied product along with copies of executed BMRs shall be submitted.

Reply submitted by the firm:

Sr. No.	Observation	Reply submitted by the firm
1.	Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.	Firm has submitted copy of inspection report dated 09-03-2023 and the report conclude as follows; "based on the physical inspection of the unit, evaluation of the documents and discussion with the technical staff, undertaking given by the CEO of the frim and considering the findings of the inspection Biogen Life Sciences, 8-Km Chakbeli Road Rawat, Rawalpindi can be considered to have acceptable compliance level subject to the condition that firm must install FTIR within one month and the same be verified by area FID."
2.	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
3.	Raw data sheets for the CDP results shall be submitted.	Submitted.
4.	Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. Clarification shall be submitted.	Firm has submitted no clarification. They only submitted official monograph for the applied formulation.
5.	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Submitted.
6.	Documents for procurement of the drug substance attested by DRAP shall be submitted.	Firm has once again submitted copy of commercial invoice No. SOK/EXP1920/0059 dated 19-11-2019 mentioning 5kg of Montelukast sodium USP, Batch No. MTS/1907004, mfg. date 07-2019 attested bi Assistant Director, I&E, DRAP, Islamabad. Invoice has mentioned Seraph pharmaceuticals as importer of the material. Firm has submitted that ADC clearance certificate of M/s Seraph pharma is submitted which is our sister concern. However, as per decision of the Registration Board regarding the Borrowing of API's for performing Product Development, R&D & Stability testing, no receiving is submitted by the firm for borrowing of API.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
873.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-KM Chakbeli Road, Rawat, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-KM Chakbeli Road, Rawat, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter No. F. 1-2/2019-Lic dated 14/02/2020 wherein they have Ampoule section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5679 dated 28-02-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 8013054618 Dated 15-02-2023
	The proposed proprietary name / brand name	Biorolac 30mg/ml injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine 30mg
	Pharmacotherapeutic Group of (API)	NSAID's
	Pharmaceutical form of applied drug	Solution for Injection for IM/IV
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	Not submitted.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Toradol 30mg/ml, USFDA Approved.
	For generic drugs (me-too status)	Toradol injection 30mg/ml, Martin Dow Marker Ltd., Reg. No. 108584.
	Name and address of API manufacturer.	Saurav Chemical Limited., 370 industrial area Phase II Panchkula, Haryana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (KTM200008, mfg. date 01-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 09 months. Batch No. KTMB100005, KTMB100006 & KTMB100007.
	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Toradol 30 mg/ml by performing quality test of Identification, Particulate matter, pH, Assay, Bacterial endotoxin test and Sterility test.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Saurav Chemical Limited., 370 industrial area Phase II Panchkula, Haryana, India.		
API Lot No.	KTMD200008.		
Description of Pack (Container closure system)	Transparent glass USP type-I Ampoules, further packed in bleach board pack containing 5 ampoules with ALU/PVC BLISTER and insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	03-07-2022	03-07-2022	03-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted that Biogen pharmaceutical is a new license facility hence no such inspection has been conducted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system are not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observations	Reply by the firm
1.		First page of form 5F is not submitted.	Submitted.
2.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted. • Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of DML No. 000911 in the name of M/s Biogen Pharmaceuticals w.e.f. 13-02-2020 and also provided change of title vide letter No. F. 1-2/2019-Lic. Dated 18-03-2021 from M/s Biogen Pharmaceuticals to M/s Biogen Life Sciences. *Not submitted.*
3.	1.3.5	Section approval letter has mentioned Ampoule section SVP (General) while the applied formulation is in vial. Justification shall be submitted.	Firm has submitted that applied formulation is in ampoule and they also have ampoule general section.
4.	1.5.4	Proposed pack size shall be submitted.	1x5's Blister contain 5 ampoule of 1 ml packed in unit carton.
5.	2.3	Table for literature references with correct information regarding the drug product with applicable fee shall be submitted.	*Revised table for literature references is submitted without fee submission.*
6.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (3) pb. 2021/3124 dated 25-06-2021 issued by Food & Drugs Administration, Punjab in the name of M/s Saurav Chemical Limited., Derabassi-Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Saibzada Ajit Singh Nagar, (Punjab) valid till 25-06-2023. *Data submitted in the dossier has mentioned Saurav Chemical Limited., 370 industrial area Phase II Panchkula, Haryana, India while the provided GMP certificate has mentioned some other address.* *Furthermore, validity of the certificate is till 25-06-2023.*

7.	3.2.S.4.1	Specifications of the drug substance by both the drug substance manufacturer and finished product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.2	Justification shall be submitted for the assay test in the analytical procedures provided by the drug substance manufacturer wherein assay test is by potentiometry while USP has mentioned HPLC method.	Firm has submitted that drug substance manufacturer used both the methods for analysis of the drug substance. They also provided analytical procedure from the drug substance manufacturer by HPLC method.
9.	3.2.S.4.3	Verification of analytical procedures of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
10.	3.2.S.4.4	• COA's from both the drug substance and drug product manufacturer with same batch number shall be submitted. • COA of the drug substance from drug product manufacturer has only one identification test while the COA of the finished product manufacturer and USP monograph has three different test. Justification shall be submitted.	Firm has submitted copies of COAs from both the drug substance manufacturer and finished product manufacturer with COA No. KTM200008, mfg. date 01-2020. Firm has submitted they perform all the identification test on drug substance. Tests are also evident from the newly submitted COA.
11.	3.2.S.7.3	• Complete real time stability of all the three batches of the drug substance shall be submitted. • Justification shall be submitted for not conducting most of the test in the stability of the drug substance i.e. Sterility, bacterial endotoxin pH etc.	Firm has submitted real time stability data for three batches the drug substance for 48 months. Firm has submitted that due to Aseptic filling of Biorolac 30mg/ml solution (Ketorolac Tromethamine) the Raw material (Ketorolac Tromethamine) is non sterile powder. That why drug substance manufacturer does not perform Bacterial Endotoxin Test &Sterility test. Other test like pH ,LOD Melting Point, Assay Impurities performed by drug substance manufacturer which are mentioned in the stability summery sheet.
12.	3.2.P.2.2	Details of the comparator product including its manufacturer, batch No. and manufacturing date etc. shall be submitted.	Product Name: Toradol 30mg/ml Injection Registration Number: 108584 Batch No: 25003 Mfg. Date:06/2022 Exp. Date:05/2024 Manufactured by :Martin Dow Marker LTD
13.	3.2.P.3.3	Scientific justification shall be submitted for not performing the terminal sterilization of the finished product.	Firm has submitted that the Finished Product was Terminally sterilized as recorded on BMR page No. 12 Which could not be mentioned here.
14.	3.2.P.5.2	Complete analytical procedures for all the tests shall be submitted.	Submitted.
15.	3.2.P.5.6	This section has mentioned manufacturer specifications. Justification shall be submitted.	Specification of Biorolac Injection is USP specs however, due to typographical mistake, instead of USP Specifications Manufacturer specifications was mentioned.

16.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not applicable. Firm has submitted commercial invoice No. SCL/2020-21/138 dated 26-09-2020 mentioning 50gm of ketorolac Tromethamine USP with batch no. KTM200008, mfg. date of 01-01-2020. *However, invoice is not attested by DRAP.* Submitted. Submitted.

Decision: Deferred for following;

- Valid copy of GMP certificate of the applicant shall be submitted.
- Clarification regarding the drug substance manufacturer shall be submitted as the submitted GMP certificate has different address than the information submitted in 3.2.S.
- Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.
- Scientific justification shall be submitted for performing the terminal sterilization of the finished product with reference to innovator drug product literature.
- Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
- Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 shall be submitted.

Firm has submitted new stability data for the applied formulation vide Dy. No. 3401 dated 22-02-2024 with submission of PKR 30,000/- vide slip No. 8968891512 Dated 19-02-2024.	
Name and address of API manufacturer.	M/s PERKIN LABORATORIES, Plot No. 94 TSIIC, Industrial estate, Medchal Dist. 501401, Telangana, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (KM-1208321, mfg. date 12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. KM-1102215, KM-1102315 & KM-1102415.

	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Toradol 30mg/ml injection, B. No.25003, mfg. date 07-2022 by performing quality test of Identification, Particulate matter, pH, Assay, Bacterial endotoxin test and Sterility test.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s PERKIN LABORATORIES, Plot No. 94 TSIIC, Industrial estate, Medchal Dist. 501401, Telangana, India.		
API Lot No.	KM-1208321.		
Description of Pack (Container closure system)	Transparent glass USP type-I Ampoules, further packed in bleach board pack containing 5 ampoules with ALU/PVC BLISTER and insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	KM T0024	KM T0025	KM T0026
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	08-07-2023	08-07-2023	08-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 106490/TS/2023 dated 11-03-2023 issued by DCA Telangana valid till 09-03-2024 is submitted by the firm.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-779348485197 dated 11-04-2022 mentioning 10kg of Ketorolac Tromethamine USP Injectable grade, B. No. KM-1208321 attested by Assistant Director, I&E, DRAP Islamabad dated 11-04-2022. Firm has also submitted 100gm loan letter from M/s Nimrall Laboratories dated 01-06-2023. *As per notification No. 14-1/2022-PEC dated 16-01-2023 of the Registration Board regarding the Borrowing of API's for performing Product Development, R&D & Stability testing, no receiving is submitted by the firm for borrowing of API.*

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
Valid copy of GMP certificate of the applicant shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

874.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	VSV-G4V-APQB dated 16-01-2024.
	Details of fee submitted	PKR 30,000/- vide slip No. 9512542272 dated: 03/11/2023.
	The proposed proprietary name / brand name	**Onolid 400mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……. …… 400mg
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.

	The status in reference regulatory authorities	ZYVOX® (linezolid) 400mg tablets, USFDA approved. ****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons****
	For generic drugs (me-too status)	Lyzon 400mg Tablet, Getz Pharma, Reg. No. 055434.
	Name and address of API manufacturer.	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India. Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. OT-LID/12/20/048, Mfg. date 12-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (OT-LID-S2-002/16, OT-LID-S2-003/16 & OT-LID-S2-004/16)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product i.e. Zoldap 400mg tablets, manufactured by Getz pharma by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Zoldap 400mg tablets, manufactured

		by Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India.		
API Lot No.	OT-LID/12/20/048.		
Description of Pack (Container closure system)	Alu/Alu Blister 0f 2 x 7's tablets with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	08/2022	08/2022	
Date of Initiation	08/2022	08/2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	

3.	2.3	Copies of executed BMR's shall be submitted.	
4.	3.2.S.4.1	Specifications of the drug substance provided by the drug product manufacturer are different from that provided by the drug substance manufacturer. Justification shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of the drug substance submitted by the drug substance manufacturer are different from USP monograph. Justification shall be submitted.	
6.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned in-house specifications while that from drug product manufacturer has mentioned USP specifications. Clarification shall be submitted.	
7.	3.2.S.4.5	Justification of specification is for some other drugs. Clarification shall be submitted.	
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	
9.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	
10.	3.2.P.8	• Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph. • Initiation date in the batch analysis and stability data sheets shall be mentioned. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Justification shall be submitted for use of 99.6 potency in the submitted raw data sheets with respect to COA submitted in 3.2.S.4.4 wherein potency of 100 is mentioned. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision of 335th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has once again submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023. ***Not valid.***
3.	2.3	Copies of executed BMR's shall be submitted.	Submitted.

4.	3.2.S.4.1	Specifications of the drug substance provided by the drug product manufacturer are different from that provided by the drug substance manufacturer. Justification shall be submitted.	Firm has submitted that specifications of drug substance by drug product manufacturer are in align with USP specifications.
5.	3.2.S.4.2	Analytical procedures of the drug substance submitted by the drug substance manufacturer are different from USP monograph. Justification shall be submitted.	Firm has submitted that updated analytical method is requested from drug substance manufacturer. However, the firm has performed analysis as per USP method.
6.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned in-house specifications while that from drug product manufacturer has mentioned USP specifications. Clarification shall be submitted.	All tests were performed as per USP monograph so the conclusion was drafted as USP Compliant.
7.	3.2.S.4.5	Justification of specification is for some other drugs. Clarification shall be submitted.	Firm has submitted that it was compilation mistake and submitted corrected justification of specifications.
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	Firm has submitted new stability studies of the drug substance.
9.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	Guidance Document for Submission of Application On Form 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use states that Pharmaceutical equivalence of the applied product could be established with the reference or comparator product. Reference pack used have following details: Zoldap Tablet 400mg Manufactured by GetzBatch # ZD505
10.	3.2.P.8	• Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph. • Initiation date in the batch analysis and stability data sheets shall be mentioned.	Firm has submitted that as per USP (905) physical tests content uniformity of film coated tablets with strengths of 25mg or less or percentage of API as compared to weight per tablet is 25% or less, is required. Firm has submitted revised stability data sheets with initiation date and is incorporated in stability data.

		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Justification shall be submitted for use of 99.6 potency in the submitted raw data sheets with respect to COA submitted in 3.2.S.4.4 wherein potency of 100 is mentioned. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted copy of commercial invoice No. 2021OT334/EXP dated 21-12-2020 in the name of M/s Biomark pharmaceuticals mentioning 25kg of linezolid IHS. However, invoice is not attested by DRAP. Firm has submitted that as identified, mistakenly the potency was taken as 99.6%. However, results measured are will within range during finished product analysis & during its stability. Firm has submitted that HPLC system used for the analysis of trial was not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 05. Registration applications of Imported deferred applications on form 5F.

875.	Name, address of Applicant / Importer	M/s Graton Pharma, Office No. 501 & 502, 5th Floor Plot 42C/2 Lane No. 8 Bukhari commercial DHA Phase-6, Karachi.
	Details of Drug Sale License of importer	License No. 160 Address: Office no. 501 & 502, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan. Address of Godown: NA Validity: 21-10-2023 Status: Drug License by way of whole sale.
	Name and address of marketing authorization holder (abroad)	M/s Jodas Expoim Pvt. Ltd., Plot No. 55, Phase-III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D) Telangana - 502279, India.
	Name, address of manufacturer(s)	M/s Jodas Expoim Pvt. Ltd., Plot No. 55, Phase-III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D) Telangana - 502279, India.
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) CoPP: Firm has submitted original, legalized copy of CoPP certificate (No: 1974295/TS/2021) dated 13-12-2021 issued by Drug Control Administration Government of Telangana, India for Doxorubicin hydrochloride for injection 10mg/vial (Lyophilized). The CoPP confirms free

		sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 18-12-2023. GMP: Copy of GMP certificate No. L. Dis No. 1967/E1/2020 dated 30-06-2020 issued by Drugs Control Administration Government of Telangana in the name of M/s Jodas Expoim Pvt. Ltd., Plot No. 55, Phase-III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D) Telangana - 502279, India wherein it is stated that the firm is following Good Manufacturing Practices as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules, 1945. The certificate is valid till 29-06-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized Authorization letter from M/s Jodas Expoim Pvt. ltd., wherein M/s Jodas Expoim confirms that M/s Graton Pharma, Office No. 501 & 502, 5th Floor Plot 42C/2 Lane No. 8 Bukhari commercial DHA Phase-6, Karachi is their agent for their products in Pakistan and they are fully authorized to register, market and sell the products. The authorization letter is valid till 31-12-2025. List of product has mentioned total of 28 products which include Doxorubicin hydrochloride 10mg and Doxorubicin hydrochloride 50mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 35493: dated 07-12-2022.
	Details of fee submitted	PKR 75,000/-: vide slip No. 0663149488 dated 15-06-2021.
	The proposed proprietary name / brand name	Cixadin Injection 10mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Doxorubicin hydrochloride …….. 10mg
	Pharmaceutical form of applied drug	Lyophilized Powder for solution for injection.
	Pharmacotherapeutic Group of (API)	Antimitotic and cytotoxic (L01DB01)
	Reference to Finished product specifications	USP Specification.
	Proposed Pack size	10ml is filled in 30ml USP type I clear glass tubular vial.

	Proposed unit price	Not mentioned.
	The status in reference regulatory authorities	Doxorubicin Hydrochloride10mg Powder for Injection, Hospira UK Limited, MHRA approved.
	For generic drugs (me-too status)	Adriblastina 10mg, Pfizer Pakistan, Reg. No. 002580.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Sterling Biotech Limited, Jambusar State Highway, Village: Masar-391 421, Ta: Padra, Dist. Vadodara, Gujrat, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data regarding nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification studies, batch analysis (061503018, 061503019 & 061503020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	24 months' real time stability data at 25°± 2°C / 60% RH ± 5% RH of 03 batches (2705, 2805 & 2905). 06 month accelerated stability data 40°C ± 2°C / 75% RH ± 5% RH of 03 batches. Batches (061403010, 061403011 & 061403012)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, formulation development, pharmaceutical development, manufacturer, batch formula, manufacturing process and process control, process validation protocols/report, specifications, analytical procedures, validation of analytical procedures, batch analysis (0070717001, 0070717002 & 0070817003), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against Aderamycin by performing quality tests including identification, pH, Assay, water content & impurities. Results of both the applied as well as reference products are in acceptable range.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	5ml clear tubular USP type I glass vial with 20mm bromobutyl rubber stoppers and 20mm aluminum flip off seals.
	Stability study data of drug product, shelf life and storage conditions	24-months real time stability data at 30°C ± 2°C / 75% ± 5% RH of 03 batches (0070817004, 0070817005 & 0070817006). 06-month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (0070817004, 0070817005 & 0070817006).

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.		Valid notarized and legalized copy of GMP certificate for of the finished product manufacturer shall be submitted.	
2.	1.1	Differential fee of 75000/- shall be submitted.	
3.	1.4.1.1	Authorization letter has mentioned the territory of Pakistan, while in module one section 1.4.1.1 has mentioned domestic and export sales. Clarification shall be submitted.	
4.	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall clearly be mentioned as this section has only mentioned 10mg.	
5.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant/concerned regulatory authority shall be submitted.	
6.	3.2	Quality overall summary as per WHO QOS-PD template shall be submitted.	
7.	3.2.S.4.2	Chromatographic condition i.e. flow rate, injection volume, column temperature et. in the assay test by the drug substance manufacturer are different from USP while the specifications provided are as of USP. Clarification shall be submitted.	
8.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	
9.	3.2.S.4.4	COAs of the drug substance from drug product manufacturer shall be submitted.	
10.	3.2.S.7.3	Real time stability data of the drug substance as per Zone Iva or Zone IVb shall be submitted.	
11.	3.2.P.2.1	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	
12.	3.2.P.2.2	Details of the reference product in CDP shall be submitted. i.e. firm name, batch number, mfg. Date & exp. Date etc.	
13.	3.2.P.5.4	COAs of the drug product for 10mg shall be submitted. COAs for 50mg is submitted instead of 10mg.	
14.	3.2.P.8.3	In use stability studies shall be submitted. Justification shall be submitted that submitted stability data is on solution form of powder form.	
15.		Justification shall be submitted whether finished Product shall be imported in combo pack or alone in powder form.	

Decision of 324th meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply by the firm
1.	Valid notarized and legalized copy of GMP certificate for of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 109360/TS/2023 dated 03-02-2023 issued by Drugs Control Administration Government of Telangana in the name of M/s Jodas Expoim Pvt. Ltd., Plot No. 55, Phase-III, Biotech Park, Karkapatla (V), Markook (M), Siddipet (D) Telangana - 502279, India wherein it is stated that the firm is following Good Manufacturing Practices as stipulated under the provisions of Schedule "M" of the Drugs and

		Cosmetics Rules, 1945. The certificate is valid till 02-02-2024.
2.	Differential fee of 75000/- shall be submitted.	Firm has submitted 75,000/- fee vide slip No. 2243020905 dated 21-12-2023.
3.	Authorization letter has mentioned the territory of Pakistan, while in module one section 1.4.1.1 has mentioned domestic and export sales. Clarification shall be submitted.	Corrected 1.4.1.1 section is submitted by the firm.
4.	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall clearly be mentioned as this section has only mentioned 10mg.	Firm has submitted following label claim; Each vial contains; Doxorubicin hydrochloride ……. 10mg
5.	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. 21062636 issued on the basis of inspection conducted on 15-16/06/2021 issued by Food & Drugs Control Administration Gujrat State, India Valid till 27-06-2024.
6.	Quality overall summary as per WHO QOS-PD template shall be submitted.	Submitted.
7.	Chromatographic condition i.e. flow rate, injection volume, column temperature et. in the assay test by the drug substance manufacturer are different from USP while the specifications provided are as of USP. Clarification shall be submitted.	Firm has submitted method equivalency report for Doxorubicin HCl. However, no clarification is submitted by the firm that why Chromatographic condition i.e. flow rate, injection volume, column temperature etc. in the assay test are different from USP while the specifications provided are as of USP.
8.	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	Submitted.
9.	COAs of the drug substance from drug product manufacturer shall be submitted.	Submitted.
10.	Real time stability data of the drug substance as per Zone Iva or Zone IVb shall be submitted.	Submitted.
11.	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	Firm has submitted that reply from manufacturer wherein they stated that the product Doxorubicin HCl injection 10mg is submitted alone in powder form without any diluent. Hence diluent details are not applicable.
12.	Details of the reference product in CDP shall be submitted. i.e. firm name, batch number, mfg. Date & exp. Date etc.	Firm has submitted that applied formulation developed by them is exactly same as that of the reference product in terms of composition (qualitative and quantitative) and the finished product specifications and results meet USP monograph and all impurity specifications and results are in accordance with ICH quality guidelines.
13.	COAs of the drug product for 10mg shall be submitted. COAs for 50mg is submitted instead of 10mg.	Submitted.
14.	In use stability studies shall be submitted. Justification shall be submitted that submitted stability data is on solution form of powder form.	Submitted. Firm has submitted that stability data is in powder form.

15.	Justification shall be submitted whether finished Product shall be imported in combo pack or alone in powder form.	Firm has submitted that product will be imported alone in powder form.

Decision: Approved as per policy of inspection of manufacturer abroad.

876.	Name, address of Applicant / Importer	**M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi.**
	Details of Drug Sale License of importer	DSL No. DHODSK(Drugs)/-809. Status: Drug License by way of whole sale. Address: M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi. Valid up to 08-12-2027.
	Name and address of marketing authorization holder (abroad)	M/s Zydus Healthcare Limited. CTS No. 460/6, I.B. Patel Road, Village Pahadi, Goregaon East, Mumbai-400063, India.
	Name, address of manufacturer(s)	M/s SP Accure Labs Pvt. Ltd., Plot No. 12, Biotech Park, Phase II, Lalgadi Malakpet (V) Shamirpet (M), Medchal – Malkajgiri (Dist.), Telangana (State), India.
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) • Colored copy of CoPP (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country. However, as per COPP certificate the product license holder is M/s SPAL Pvt. Ltd., India. • Copy of GMP certificate No. 82237/TS/2022 dated 03-03-2022 issued by Drugs Control Administration, Telangana in the name of M/s SPAL Private Limited valid till 02-03-2023 is submitted.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of sole distribution letter between M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi and M/s Zydus Healthcare Limited, located at Zydus corporate park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandinagar Highway, Ahmad Abad, India. Document has mentioned that M/s Zydus Healthcare Limited, is MAH. However, CoPP has mentioned M/s SPAL Pvt. Ltd., India as MAH for the product. Agreement has mentioned that M/s Wellociti upon registration of products in Pakistan shall be the sole authorized importer for the products (14) in Pakistan. Firm has also submitted copy of contract manufacturing agreement between M/s Zydus Healthcare Limited and M/s SP Accure Labs Pvt. Ltd., wherein M/s Zydus Healthcare Limited is engaged in sale marketing and distribution of wide range of pharmaceutical products in various countries. While M/s SP Accure Labs Pvt. Ltd., is engaged in

		manufacturing, sales and distribution of pharmaceutical products in India.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 23761: dated 21-11-2023.
	Details of fee submitted	PKR 150,000/-: vide slip No. 7551511337 dated 07-08-2023.
	The proposed proprietary name / brand name	**Cisplat 50.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml vial contains: Cisplatin …… 50mg.
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion.
	Pharmacotherapeutic Group of (API)	Other Antineoplastic Agents, Platinum compound.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 vials in a carton along with pack insert.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Cisplatin 50mg/vial, USFDA approved.
	For generic drugs (me-too status)	Cipintu concentrated solution for infusion, Himmel pharma, Reg. No. 099486.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Sun pharmaceutical Industries Limited, A-7/A-8, M.I.D.C., Industrial Area, Ahmednagar – Maharashtra, India.

		Copy of GMP certificate No. NEW-WHO-GMP/CERT/NKD/72512/2018/11/24746 dated 30-08-2018 issued by Food & Drugs Administration M.S. Bandra - Mumbai valid till 29-08-2021 is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 72 months' real time stability data at 25°± 2°C / 60% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015). • 06 month accelerated stability data 40°C ± 2°C / 75% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against product i.e. Cisplatin NeoCorp 1mg/ml, Lot No. JG5128 MAH Hexal AG Industries by performing the following tests; Description, Identification, pH, Assay & Related substances.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	10ml amber 20mm collar vials (flat bottoms) with 20mm 4432/50 gray fluorotec B2 coating westarrs serum stopper and sealed with 20mm easy to open C/L Alu. Seals with matt finish plastic purple.
	Stability study data of drug product, shelf life and storage conditions	• 36-month real time stability data at 30°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)). • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)).

Evaluation by PEC:

Sr. No.	**Section**	Observations	Reply by the firm.
1.	•	• Notarized agreement shall be submitted. • Address of the marketing authorization holder mentioned in 1.4 and that mentioned in sole distribution agreement are different. Clarification shall be submitted.	
2.		Valid, notarized and legalized copy of GMP certificate of the manufacturer shall be submitted.	
3.	•	• Notarized and legalized copy of CoPP certificate shall be submitted.	

		• Submitted CoPP has mentioned M/s SPAL Pvt. Ltd., India as product license holder while the agreement of the M/s Wellociti is with M/s Zydus Healthcare Limited. Clarification shall be submitted.	
4.	1.4.1	Section 1.4.1 has mentioned domestic and export sales while the sole distribution agreement has mentioned in Pakistan only. Clarification shall be submitted.	
5.	3.2.S.4.2	BP monograph has mentioned injection volume of 20µl while the specifications submitted by both the drug substance and drug product manufacturer has mentioned 10µl. clarification shall be submitted.	
6.	3.2.P.1	Qualitative composition of the applied formulation is different from innovator with respect to mannitol. Clarification shall be submitted.	
7.	3.2.P.2.2	Justification shall be submitted for not performing uniformity of content, sterility and bacterial endotoxin test in PE studies.	

Decision of 333rd meeting of registration Board: Deferred for submission of reply to above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observations	Reply by the firm.
1.	• Notarized agreement shall be submitted. • Address of the marketing authorization holder mentioned in 1.4 and that mentioned in sole distribution agreement are different. Clarification shall be submitted.	Firm has once again submitted coloured copy of agency agreement. Firm has submitted that SPAL is manufacturer, as per India FDA rule this is third party manufacturing product so license holder is SPAL. They further submitted that they also shared a letter for relationship between Zydus and SPAL. *As per submitted CoPP certificate (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country.* *However, as per COPP certificate the product license holder is M/s SPAL Pvt. Ltd., India.*
2.	Valid, notarized and legalized copy of GMP certificate of the manufacturer shall be submitted.	Coloured copy of GMP certificate No. 109200/TS/2023 dated 28-03-2023 issued by Drugs Control Administration, Telangana in the name of M/s SPAL Private Limited valid till 26-03-2024 is submitted. *GMP certificate is submitted is coloured copy*.
3.	• Notarized and legalized copy of CoPP certificate shall be submitted. • Submitted CoPP has mentioned M/s SPAL Pvt. Ltd., India as product license holder while the agreement of the M/s Wellociti is with M/s Zydus Healthcare Limited. Clarification shall be submitted.	*Not submitted.* Firm has submitted that SPAL is manufacturer, as per India FDA rule this is third party manufacturing product so license holder is SPAL. They further submitted that they also shared a letter for relationship between Zydus and SPAL.
4.	Section 1.4.1 has mentioned domestic and export sales while the sole distribution	Firm has submitted that agreement between Zydus and Wellociti is for Pakistan sale only. SPAL is contract manufacturer of Zydus for domestic as

	agreement has mentioned in Pakistan only. Clarification shall be submitted.	well as export. *Section 1.4.1 from the applicant had mentioned domestic and export sales while agency agreement was for Pakistan only.*
5.	BP monograph has mentioned injection volume of 20µl while the specifications submitted by both the drug substance and drug product manufacturer has mentioned 10µl. clarification shall be submitted.	Firm has submitted that 20µl injection volume was mentioned for related substances and for assay it was mentioned as 10µl. they also submitted BP monograph for the same.
6.	Qualitative composition of the applied formulation is different from innovator with respect to mannitol. Clarification shall be submitted.	Firm has submitted that SPAL has chosen Neocorp as reference product which does not contain mannitol in its composition. SPAl product is similar to Neocorp which is the innovator. So, the composition of the applied formulation which was applied in module 3.2.P.1 does not contain mannitol. They also submitted pictures of Neocorp product. However, the language is other than English that could not be read.
7.	Justification shall be submitted for not performing uniformity of content, sterility and bacterial endotoxin test in PE studies.	Firm has submitted that PE studies only contains the information regarding the test vs RLD qualitative information. Therefore, uniformity of content, sterility and bacterial endotoxin test will not be reflected in the PE studies.

Decision: Deferred for following;

- **Notarized agreement shall be submitted.**
- **Valid, Notarized copy of CoPP certificate shall be submitted.**

Case No. 06. Registration applications of locally manufactured deferred human application on form 5.

877.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kem- Mont 10mg Tablet
	Composition	Each chewable tablet Contains: Montelukast (as sodium)…….10mg
	Diary No. Date of R & I & fee	Dy. No. 40388; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 30's, 40's, 50's,60's, 70's, 80's, 90's, 100; Rs. 100 per tablet
	Approval status of product in Reference Regulatory Authorities.	Singulair Tablet 10 mg of M/S MSD (USFDA Approved)
	Me-too status	Montiget 10 mg tablets of M/s Getz Pharma (Reg.# 034838)
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required. • Provide proof of approval of me-too product (name registration number and name of company) by DRAP. • Revise "Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.
	Decision of 296th meeting of RB	Deferred for:

		• Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. • Proof of approval of me-too product (name registration number and name of company) by DRAP. • Revision of Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm submitted Rs. 7,500/- fee (Challan: 9322242273) • The firm did not adjust the weight of montelukast sodium in master formula as salt factor. • The firm included film-coating in the master formula and manufacturing outlines. The firm shall submit all the required documents (Form 5, master formula with adjustment of the weight of montelukast sodium as salt factor, complete specifications including testing method) for film-coated tablet.
	Decision of 313th meeting of Reg. Board.	Deferred for submission of all the required documents (Form 5, master formula with adjustment of the weight of montelukast sodium as salt factor, complete specifications including testing method) for film-coated tablet.
	Reply submitted by the firm.	Firm has submitted revised form 5, master formula with adjustment of the weight of montelukast sodium as salt factor, complete specifications including testing method as per USP along with submission of 22,500/- fee vide slip no. 125118927 dated 17-01-2024. Firm has also requested for a pack size of 14's. Revised label claim is as under; **Each film coated tablet Contains:** **Montelukast (as sodium)…….……10mg**
	Evaluation by PEC	Firm has submitted copy of inspection report dated 18-09-2023 wherein it is concluded that overall GMP compliance was found at an acceptable level with directions to address the recommendations mentioned at the time of inspection.
	Decision: Approved with following label claim; **Each film coated tablet Contains:** **Montelukast (as sodium)…….……10mg**	
878.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemadol-P 37.5/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCl …… 37.5mg Paracetamol …… 325mg
	Diary No. Date of R & I & fee	Dy. No. 40379; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Rs. 190/-
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too status	Tril-P Tablet. Reg. No. 78181
	GMP status	Latest GMP inspection report is required.

	Remarks of the Evaluator(IX)	• First page of Form 5 is missing. • Revise tramadol as HCl to tramadol HCl and mention correct quantity of tramadol HCl, i.e., 37.5mg in Master formula.
	Decision of 296th meeting of RB	Deferred for: • Submission of latest GMP inspection report. • Submission of Form 5 (first page). • Revision of tramadol as HCl to tramadol HCl (label claim and composition) and mentioning the correct quantity of tramadol HCl, i.e., 37.5mg in Master formula.
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm did not submit Form 5. • The firm revised tramadol as HCl to tramadol HCl in the composition and mentioned the correct quantity of tramadol HCl, i.e., 37.5mg in Master formula. Revision of label claim is required. • The firm submitted Rs. 7,500/- fee (Challan: 35326160)
	Decision of 313th meeting of Reg. Board.	Deferred for revision of label claim.
	Reply submitted by the firm.	Firm has submitted revised form 5, master formula with along with submission of 22,500/- fee vide slip no. 33874976 dated 17-01-2024. Firm has also requested for a pack size of 30's in a unit pack. Revised label claim is as under; **Each film coated tablet Contains:** **Tramadol HCl……..…. 37.5mg** **Paracetamol ……..…. 325mg**
	Evaluation by PEC	Firm has submitted copy of inspection report dated 18-09-2023 wherein it is concluded that overall GMP compliance was found at an acceptable level with directions to address the recommendations mentioned at the time of inspection.
	Decision: Approved with following label claim; **Each film coated tablet Contains:** **Tramadol HCl……. 37.5mg.** **Paracetamol ……..…. 325mg.**	
879.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Fluzipine 6/25mg Capsule.
	Composition	Each Capsule Contains: Olanzapine ……6mg Fluoxetine ……25mg
	Diary No. Date of R & I & fee	Dy. No. 10141; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Co-Depricap 6/25 Capsule by NabiQasim Karachi. Reg. No. 76135.

	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator [IX]	The firm revised Fluoxetine…25mg to Fluoxetine as HCL…25mg without submission of applicable fee.
	Decision of 296th meeting of Registration Board.	Deferred for submission of applicable fee for revision of salt form.
	Submission by the firm.	Firm has submitted fee of Rs. 30,000/- vide slip No. 907396469 dated 26-01-2024. **Revised label claim is as under;** **Each Capsule Contains:** **Olanzapine ……6mg** **Fluoxetine as HCl ……25mg**
	Remarks of the Evaluator.	Current GMP status and Section approval of the firm could not be confirmed.
	Decision: Approved with following label claim; **Each Capsule Contains:** **Olanzapine ……6mg.** **Fluoxetine as HCl ……25mg.** **Registration letter will be issued after submission of valid GMP certificate of the applicant and section approval letter.**	
880.	Name and address of manufacturer/ Applicant	M/s Max Pharmaceuticals, Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Meroxat 20mg Tablets.
	Composition	Each Tablet Contains: Paroxetine Hydrochloride……20mg
	Diary No. Date of R & I & fee	Form-5 Dy. No 30787 dated 12-09-2018 Rs.20,000/- Dated 12-09-2018.
	Pharmacological Group	Selective serotonin reuptake inhibitors.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil (10mg, 20mg, 30mg, 40mg) film coated tablet USFDA Approved
	Me-too status	Frais Tablet 20mg by M/s Bio-Mark Pharmaceuticals (Reg. # 082658)
	GMP status	The firm was inspected on 26-06-2019 and conclusion of inspection was: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm was advise to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator	Letter of deficiencies sent on 05-11-2020 and reminder on 27-01-2021 but no reply received yet • The reference formulation is film coated while you have applied for uncoated tablets. Revise the label claim as per reference formulation along with submission of applicable fee. Moreover, you have applied the label claim not considering the salt factor. Revise the label claim as per reference formulation without considering the salt factor along with submission of applicable fee. • You have mentioned methylene chloride in your formulation which is a banned excipient as per 286th Registration Board decision, clarify? • Manufacturing outline for sitagliptin phosphate monohydrate and metformin hydrochloride is submitted. Submit manufacturing outline for the applied product
	Decision of 307th meeting of Registration Board.	Deferred for following: • Revision of label claim and master formulation from uncoated tablets to film coated tablets along with submission of applicable fee. Furthermore, revision of label claim considering the salt factor. • Clarification regarding use of methylene chloride in formulation which is a banned excipient as per decision of 286th meeting of Registration Board. • Submission of manufacturing outline for the applied product
	Submission by the firm.	• Firm has submitted revised form 5 with submission of **30,000/-** fee vide slip No. 6727742815 dated 22-08-2024. • Firm has also submitted revised master formula wherein they have removed methylene chloride and the manufacturing outlines for the applied formulation. • Copy of GMP certificate No. F. 3-106/2023-Addl. Dir. (QA & LT-I)-44 dated 16-06-2023 is submitted wherein Tablet general section is also mentioned. Section approval letter No. F. 1-103/2005-Lic (Vol-II) dated 07-07-2021 for Tablet general section is also submitted. **Revised label claim is as under;** **Each film coated tablet contains:** **Paroxetine as Hydrochloride……20mg**
	Remarks of the Evaluator.	
	Decision: Approved with following label claim; **Revised label claim is as under;** **Each film coated tablet contains:** **Paroxetine as Hydrochloride……20mg**	
881.	Name and address of manufacturer/ Applicant	M/s Mega Pharmaceuticals (Pvt.) Limited, 27-km, Raiwind Road, Lahore (Tablet General, Antibiotics).
	Brand Name + Dosage Form + Strength	Eteri 120mg Tablets.
	Composition	Each Film Coated Tablet Contains: Etoricoxib ……120mg
	Diary No. Date of R & I & fee	Dy. No 11354 dated 05-03-2019; Rs. 20,000/- dated 04-03-2019.
	Pharmacological Group	Anti-inflammatory & Anti-rheumatic products, non-

		steroids.
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA 120 mg film-coated tablets, MHRA approved
	Me-too status.	Could not be confirmed.
	GMP status.	GMP certificate issued on 30-10-2018 on the basis of inspection conducted on 09-07-2018.
	Remarks of the Evaluator [XIII].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Firm has also provided T-cox, Recox, Terib, Xiba,& E-cox as alternative brand names.
	Decision of 308th meeting of Registration Board:	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me too status) along with registration number, brand name and name of firm OR else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 293rd meeting of registration Board.
	Submission by the firm.	Firm has submitted following product as me too; Starcox 120mg tablets, Getz pharma, Reg. no. 105294.
	Remarks of the Evaluator	• Current GMP status of the firm could not be confirmed. • Etoricoxib 120mg is a stability molecule, and at the time of application submission me too product was not registered. Firm has now submitted me too status for the applied formulation. Submitted me too was also approved in 286th meeting after onsite inspection of the submitted stability data for the applied formulation.
	Decision: The current application is disposed of as per decision of the Registration Board in its 329th meeting held on 6th to 8th June, 2023 regarding the submission of stability studies for molecules applied on form 5 or 5D requiring stability The applicant shall submit its product development and stability data on Form-5F which will be considered on its turn in queue of Form 5F.	
882.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	C-Sporin 10mg Capsule
	Diary No. Date of R & I & fee	Dy. No. 3322-E. 14-04-2017. Rs: 20,000/-: 14-04-2017.
	Composition	Each capsule contains Cyclosporine …….…….10mg
	Pharmacological Group	Immunosuppressant
	Type of Form.	Form 5
	Finished product Specification.	USP Specifications
	Pack size & Demanded Price	As per SRO 60‘s
	Approval status of product in Reference Regulatory Authorities.	Availability as hard gelatin capsule could not be confirmed
	Me-too status.	Not confirmed as hard gelatin capsule Registered as soft gelatin capsule (imported) for Novartis
	GMP status.	Inspection report dated 16-02-2017 recommended the

		grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Evidence of approval of applied formulation as hard gelatin capsule in reference regulatory authorities. • Me-too status
	Decision of 270th meeting of Registration Board:	Deferred for following submission • Evidence of approval of applied formulation as hard gelatine capsule in reference regulatory authorities. • Evidence of Me-too status. • Confirmation of requirement of separate manufacturing facility for immunosuppressant's.
	Submission by the firm.	• Firm has submitted CYCLOSPORIN SANDOZ® CAPSULES 25mg, 50mg and 100mg TGA approved (ARTG ID 186358) as RRA for the applied formulation. • Firm has also submitted Neocyspin 100mg capsule of M/s Biocare Pharma, Reg. no. 053889 as me too products. • Firm has submitted that this molecule falls in general category, so they have general capsule area for its manufacturing.
	Remarks of the Evaluator	• Label claim in the previous minutes is Each capsule contains … 10mg which may be a typographic error. • However, both the submitted RRA and me too are in soft gelatin capsule while the applied formulation is hard gelatin capsule. • Current GMP status of the firm could not be confirmed.
	Decision: Registration Board disposed-off the instant application as neither evidence of approval of applied formulation in reference regulatory authorities is available nor any generic is registered previously in Pakistan.	
883.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	C-Sporin 50mg Capsule
	Diary No. Date of R & I & fee	Dy. No. 3220-C: 14-04-2017 Rs: 20,000/-: 14-04-2017
	Composition	Each capsule contains Cyclosporin…….50mg
	Pharmacological Group	Immunosuppressant
	Type of Form.	Form 5
	Finished product Specification.	USP Specifications
	Pack size & Demanded Price	As per SRO 50's
	Approval status of product in Reference Regulatory Authorities.	Availability as hard gelatin capsule could not be confirmed
	Me-too status.	Bioral by Allmed Labs (Could not be confirmed whether it is available as hard gelatin or soft gelatin capsule)
	GMP status.	Inspection report dated 16-02-2017 recommended the grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Evidence of approval of applied formulation as hard gelatin capsule in reference regulatory

		authorities. • Me-too status
	Decision of 270th meeting of Registration Board:	Deferred for following submission • Evidence of approval of applied formulation as hard gelatine capsule in reference regulatory authorities. • Evidence of Me-too status. • Confirmation of requirement of separate manufacturing facility for immunosuppressant's.
	Submission by the firm.	• Firm has submitted CYCLOSPORIN SANDOZ® CAPSULES 25mg, 50mg and 100mg TGA approved (ARTG ID 186358) as RRA for the applied formulation. • Firm has also submitted Neocyspin 50mg capsule of M/s Biocare Pharma, Reg. No. 072552 as me too products. • Firm has submitted that this molecule falls in general category, so they have general capsule area for its manufacturing.
	Remarks of the Evaluator	Both the submitted RRA and me too are in soft gelatin capsule while the applied formulation is hard gelatin capsule. • Current GMP status of the firm could not be confirmed.
	Decision: Registration Board disposed-off the instant application as neither evidence of approval of applied formulation in reference regulatory authorities is available nor any generic is registered previously in Pakistan.	
884.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	C-Sporin 25mg Capsule
	Diary No. Date of R & I & fee	Dy. No. 3220-D: 14-04-2017 Rs: 20,000/-: 14-04-2017
	Composition	Each capsule contains Cyclosporin…….25mg
	Pharmacological Group	Immunosuppressant
	Type of Form.	Form 5
	Finished product Specification.	USP Specifications
	Pack size & Demanded Price	As per SRO 50's
	Approval status of product in Reference Regulatory Authorities.	Availability as hard gelatin capsule could not be confirmed
	Me-too status.	Bioral by Allmed Labs (Could not be confirmed whether it is available as hard gelatin or soft gelatin capsule)
	GMP status.	Inspection report dated 16-02-2017 recommended the grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Evidence of approval of applied formulation as hard gelatin capsule in reference regulatory authorities. • Me-too status
	Decision of 270th meeting of Registration Board:	Deferred for following submission • Evidence of approval of applied formulation as hard gelatine capsule in reference regulatory authorities. • Evidence of Me-too status. • Confirmation of requirement of separate

		manufacturing facility for immunosuppressant's.
	Submission by the firm.	• Firm has submitted CYCLOSPORIN SANDOZ® CAPSULES 25mg, 50mg and 100mg TGA approved (ARTG ID 186358) as RRA for the applied formulation. • Firm has also submitted Neocyspin 25mg capsule of M/s Biocare Pharma, Reg. No. 053888 as me too products. • Firm has submitted that this molecule falls in general category, so they have general capsule area for its manufacturing.
	Remarks of the Evaluator	Both the submitted RRA and me too are in soft gelatin capsule while the applied formulation is hard gelatin capsule. • Current GMP status of the firm could not be confirmed.
	Decision: Registration Board disposed-off the instant application as neither evidence of approval of applied formulation in reference regulatory authorities is available nor any generic is registered previously in Pakistan.	
885.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	Azobax 500mg Capsule
	Diary No. Date of R & I & fee	Dy. No: 516-A: 20-04-2017 Rs: 20,000/-: 20-04-2017
	Composition	Each capsule contains Azithromycin dehydrate eq. to Azithromycin……..500mg
	Pharmacological Group	Macrolide
	Type of Form.	Form 5
	Finished product Specification.	USP Specifications
	Pack size & Demanded Price	As per SRO 6's, 10's
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status.	Zygrel Capsule by Searle
	GMP status.	Inspection report dated 16-02-2017 recommended the grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Evidence of approval of applied formulation in reference regulatory authorities. • Pack size of 6's and 10's is not justified as the recommended dose for azithromycin 500mg is once daily for 3 days. • Firm has changed the brand name from Azobax to Azip capsule.
	Decision of 270th meeting of Registration Board:	Deferred for evidence of approval in reference regulatory authorities.
	Submission by the firm.	Firm has submitted that the applied formulation is registered in the European country Bulgaria. They also submitted a document which is in some language other than English.
	Remarks of the Evaluator	• As per requirement of the Registration Board, three European countries shall have the registration of the applied formulation.

		• RRA of the applied formulation could not be confirmed. • Current GMP status of the firm could not be confirmed.
	Decision: The Board deferred that case for submission of valid DML and valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority; **a. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **b. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **c. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **d. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
886.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	Dorinem 250mg Injection
	Diary No. Date of R & I & fee	Dy. No.: Rs: 20,000/-: 13-04-2017
	Composition	Each vial contains Doripenem monohydrate equivalent to Doripenem …….250mg
	Pharmacological Group	Antibiotic (Carbapenem)
	Type of Form.	Form 5
	Finished product Specification.	-
	Pack size & Demanded Price	As per SRO 10‘s
	Approval status of product in Reference Regulatory Authorities.	Doribax by Shionogi Inc. (USFDA Approved)
	Me-too status.	Not confirmed
	GMP status.	Inspection report dated 16-02-2017 recommended the grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Me-too status • Firm has claimed in house spec‘s without providing data as per requirements of 267th RB meeting
	Decision of 270th meeting of Registration Board:	Deferred for following submissions of evidence of me-too status OR Application on Form 5-D alongwith differential fee of Rs: 30,000/ and submission of stability study data as per the guidelines approved by Registration Board in its 251st meeting.
	Submission by the firm.	Firm has submitted following product as me too; Ronim 250mg injection, Genix pharma, Reg. No. 093113.
	Remarks of the Evaluator	• Doripenem monohydrate is a stability molecule, and at the time of application submission me too product was not registered. Firm has now submitted me too status for the applied formulation. Submitted me too was also approved in 277th meeting after onsite inspection of the submitted stability data for the applied formulation. • Current GMP status of the firm could not be confirmed.

	Decision: The current application is disposed off as per decision of the Registration Board in its 329th meeting held on 6th to 8th June, 2023 regarding the submission of stability studies for molecules applied on form 5 or 5D requiring stability The applicant shall submit its product development and stability data on Form-5F which will be considered on its turn in queue of Form 5F.	
887.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals, Plot # 26, Street # s.s.-3, National Industrial Zone (RCCI) Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	Dorinem 500mg Injection
	Diary No. Date of R & I & fee	Dy. No.: Rs: 20,000/-: 13-04-2017
	Composition	Each vial contains Doripenem monohydrate as Doripenem…….500mg
	Pharmacological Group	Antibiotic (Carbapenem)
	Type of Form.	Form 5
	Finished product Specification.	-
	Pack size & Demanded Price	As per SRO 10‘s
	Approval status of product in Reference Regulatory Authorities.	Doribax by Shionogi Inc. (USFDA Approved)
	Me-too status.	Not confirmed
	GMP status.	Inspection report dated 16-02-2017 recommended the grant of two additional sections
	Remarks of the Evaluator.	Letter of shortcoming was issued on 8th May and the reply received is still deficient in • Me-too status • Firm has claimed in house spec‘s without providing data as per requirements of 267th RB meeting
	Decision of 270th meeting of Registration Board:	Deferred for following submissions of evidence of me-too status OR Application on Form 5-D alongwith differential fee of Rs: 30,000/ and submission of stability study data as per the guidelines approved by Registration Board in its 251st meeting.
	Submission by the firm.	Firm has submitted following product as me too; Ronim 500mg injection, Genix pharma, Reg. No. 088904.
	Remarks of the Evaluator	• Doripenem monohydrate is a stability molecule, and at the time of application submission me too product was not registered. Firm has now submitted me too status for the applied formulation. Submitted me too was also approved in 277th meeting after onsite inspection of the submitted stability data for the applied formulation. • Current GMP status of the firm could not be confirmed.
	Decision: The current application is disposed of as per decision of the Registration Board in its 329th meeting held on 6th to 8th June, 2023 regarding the submission of stability studies for molecules applied on form 5 or 5D requiring stability The applicant shall submit its product development and stability data on Form-5F which will be considered on its turn in queue of Form 5F.	
888.	Name and address of manufacturer/ Applicant	**M/s Ipram International Pharmaceuticals plot # 26, street # S.S-3 national industrial zone.**
	Brand Name + Dosage Form + Strength	Viroquin injection 200mg/5ml
	Diary No. Date of R & I & fee	Dy. No. 6391 dated 06/04/2020 Rs. 20,000/- 06-04-2020

	Composition	Each 5ml Ampoule Contains: Chloroquine Phosphate …… 200mg
	Type of Form.	Form 5
	Pack size & Demanded Price	As per SRO
	GMP status.	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018.
	Decision of 295th meeting of Registration Board:	Registration Board deferred the case for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Submission by the firm.	Firm has submitted two pages from internet and they also submitted that this product is available in France. One of the page has mentioned Belgium.
	Remarks of the Evaluator	• ***However, in ANSM, France and in the regulatory authority of Belgium there is no product in injection formulation of chloroquine phosphate.*** • ***Current GMP status of the firm could not be confirmed.***
	Decision: Deferred for following: • **Submission of valid DML** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
889.	Name and address of manufacturer/ Applicant	**M/s. Ipram international Plot No. 26, S.S-3., National industrial zone Rawat, Islamabad.**
	Brand Name + Dosage Form + Strength	Spasmo- P Injection 40mg
	Diary No. Date of R & I & fee	Dy. No. 8694; 13-07-2017; Rs. 20,000/-
	Composition	Each 4ml ampoule contains: Phloroglucinol hydrated ……...…40mg Trimethylphloroglucinol……..…0.04mg
	Pharmacological Group	Antispasmodic
	Type of Form.	Form 5
	Finished product Specification.	Manufacturer Specifications.
	Pack size & Demanded Price	6's (4ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Couldn't confirmed
	Me-too status.	Couldn't confirmed
	GMP status.	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018
	Remarks of the Evaluator.	Applied formulation is not present in available USP & BP. • Terminal sterilization is not being performed. • Evidence of International Availability • Evidence of me too with registration number.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation. • Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.

		• Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC.	Applicant has submitted the following: • Terminal sterilization is not being carried out because it is not necessary or ideal to sterilize any product terminally nor it is the only & one way of sterilization. • Our sterilization process is filtration sterilization. • Evidence of approval in RRA. Not Verifiable. • Evidence of Me Too. Brand Name: Spasrid Injection by Barrett Hodgson. Registration No. 034744.
	Decision of 292nd meeting of Registration Board.	• Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation. • Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Submission by the firm	• Firm has submitted that the product is heat sensitive so filtration method is used as the mode of filtration to avoid the product degradation. • Firm has submitted Spadix Injection, Tabros Pharma, Reg. No. 029528 as me too product. • SPASFON, solution for injection in ampoule, ANSM france approved is reference product.
	Evaluation by PEC.	• Label claim of the reference product has mentioned Hydrated Phloroglucinol 40.00 mg Quantity corresponding to anhydrous Phloroglucinol at 31.12 mg. • Current GMP status of the firm could not be confirmed.
	Decision: Deferred for the submission of valid DML	
890.	Name and address of manufacturer / Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name +Dosage Form + Strength	KETOCARE 30mg/1ml Injection (IV)
	Composition	Each 1ml Ampoule Contains; Ketorolac Trometamol BP……30mg
	Diary No. Date of R& I & fee	Dy.No.16973 dated 07-03-2019; Fee Rs. 50,000 paid vide slip No. 0740092 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5 ampoules of 1ml each. As per SRO

	Approval status of product in Reference Regulatory Authorities.	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved.
	Me-too status	Cadlec 30mg/ml Injection IM/IV Reg. No. 095892 M/s Brookes Pharma Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator.	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board, Wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section.
	Decision of 323rd RB Meeting	Deferred for clarification of sterilization method used for the applied formulation.
	Remarks of the Evaluator.	The firm vide letter No. CSH/2023/Reg-17 dated 22.01.2024 has submitted a European Patent No. EP2616064B1 filed by RTU Pharmaceuticals Naples FL USA. In the patent it is mentioned that product is terminally sterilized. In the patent formulation Ethanol is used indicating that terminal sterilization is possible for formulations containing ethanol.
	Decision: Approved.	
891.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CB SOLE-S LOTION
	Composition	Each ml contains: - Clobetasol propionate…...0.5mg Salicylic acid…….20mg
	Diary No. Date of R & I & fee	Dy. No.1110 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577595 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Corticosteroid / antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Clobetred-S Each ml contains: - Clobetasol ..... 0.525mg Salicylic Acid .... 20mg) of Mass pharma, Lahore. Registration No. 037636
	GMP status	Not provided

	Remarks of the Evaluator (PEC-XVII)	• Topical Lotion (General) Section & Cream/ointment (General) Section are mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise manufacturing outlines as per applied formulation since betamethasone valerate is mentioned in manufacturing outlines. • Provide evidence of approval of applied formulation in reference regulatory authorities which were declared/adopted by the Registration Board in its 275th meeting. • Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer as the me-too provided has different composition than the applied formulation. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision of 323rd meeting of Registration Board	Deferred for: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm me-too provided has different composition than the applied formulation. • Evidence of approval of requisite manufacturing facilities/section by Licensing division for topical solution preparation. • Revision of manufacturing outlines as per applied formulation since Betamethasone valerate is mentioned in manufacturing outlines submitted by the firm.
	Submission by the firm.	• Firm has submitted revised formulation as per RRA and stated that due to typographic error, clobetasole was mentioned instead of Betamethasone with submission of 7500/- fee vide slip No. 773288785770 dated 09-12-2022. • Health Canada approved formulation i.e. Prratio-TOPISALIC, Betamethasone Dipropionate (0.5 mg / g as base) and Salicylic Acid (20 mg / g) is provided as evidence of RRA and Betasalic otion of M/s Atco pharma, Reg. No. 028097 is provided as me too for the applied formulation. • Firm has submitted copy of letter No. F.1-51/2005-Lic (Vol-I) dated 17-07-2019 wherein Topical Lotion (General) Section & Cream/ointment (General) Section are mentioned & cream & ointment (steroidal) section are approved. **Revised formulation is as under;** **Each gram contains:** **Betamethasone Dipropionate eq. to Betamethasone ……..…..0.5mg** **Salicylic acid ……..……20mg**

	Remarks of the Evaluator	• Revised form 5 with master formula and manufacturing outlines shall be submitted. • Differential fee of 22,500/- for revision of label claim shall be submitted. • Submitted me too has different composition from the applied formulation. • Evidence of separate dispensing booth in the concerned section shall be submitted.
	Decision of 331st meeting of Registration Board	Deferred for following: • Revised form 5 with master formula and manufacturing outlines shall be submitted. • Differential fee of 22,500/- for revision of label claim shall be submitted. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Evidence of separate dispensing booth in the concerned section shall be submitted.
	Submission by the firm.	• Firm has submitted revised form 5 with master formula and manufacturing outlines. • Differential fee of 22500/- vide slip No. 7140913654 dated 27-02-2024. • Corbesalate Lotion, Cortex Pharmaceuticals, Reg. No. 081631. • Firm has also submitted inspection report.
	Remarks of the Evaluator	
	Decision: Registration Board did not accede to the request of firm for change of applied formulation in terms of drug substance hence Board decided to declare the application as disposed off.	

Case No. 07. Registration applications of locally manufactured deferred veterinary application on form 5.

892.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Trinex Water Soluble Powder.
	Composition	Each gm contains: Trimethoprim……..80mg Sulphadiazine……420mg
	Diary No. Date of R & I & fee	Dy.No.29704; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Di hydrofolate reductase inhibitor/ Antibacterial
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer specifications.
	Pack size & Demanded Price	100g, 250g, 500g, 1kg, 2.5 kg packed in polyethylene bag and put into plastic jar, 5gm and 10gm sachet & Decontrolled.
	Me-too status.	Cotrim 50 WSP of M/s Prix Pharma (Reg. # 043295)
	GMP status.	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Remarks of the Evaluator XIII.	General Oral Powder section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision of 293rd meeting of Registration Board:	Deferred for confirmation of rationale of formula since it is not in standard ratio i.e. 1:5.
	Submission by the firm.	Firm has submitted that same formulation is available in the market with the name of Cotrim 50 powder of M/s Prix

		Pharmaceutica having Registration number 043295. They further requested to consider their product for registration in the upcoming meeting of registration board.
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.
	Decision: Approved. The firm will apply for standardization of formulation in standard ratio i.e. 1:5. **The board also diorected to ask all MA hiolders of this formulation to standardize accordingly.** **The applicable fee will be deposited for all cases including instant one.**	
893.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Oxycloz Plus Drench
	Composition	Each gram contains: Oxfendazole……62.50mg Oxyclozanide……..22.65mg Cobalt Sulphate……1.67mg Sodium Selenite……0.50mg
	Diary No. Date of R & I & fee	Dy.No.442 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status.	Punch Drench of M/s Selmore Pharma (Pvt.) Ltd., Lahore 032206 if each 100ml contains is applied.
	GMP status.	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	Applied as drench while gm/ mg is applied in composition.
	Decision of 296th meeting of Registration Board:	Deferred for following reasons: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Formulation is applied as drench while gm/ mg is applied in composition.
	Submission by the firm.	Firm has revised their label claim with submission of 5000/- vide deposit slip No. 2030994 dated 01-04-2021 from Each gram contains to Each ml contain. They also provided Punch Drench of M/s Selmore Pharma, Reg. No. 032206 as me too for the applied formulation. Revised label claim is as under: Each ml contains: Oxfendazole……62.50mg Oxyclozanide……..22.65mg Cobalt Sulphate……1.67mg Sodium Selenite……0.50mg
	Remarks of the Evaluator PEC-XIII	Current GMP status of the firm could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	• Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.

		• GMP certificate has also mentioned Drench section general
	Remarks of the Evaluator PEC-XIII	Fee required for revision of label claim shall be submitted.
	Decision: Approved with innovator's specifications. **Registration letter will be issued after submission of 7500/- fee for change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
894.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Clozasol Plus Drench.
	Composition	Each 100ml contains: Levamisole (HCl)……1.50gm Oxyclozanide……..3gm Cobalt Sulphate……0.167gm Sodium Selenite……...0.05gm
	Diary No. Date of R & I & fee	Dy. No. 444 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status.	Could not be confirmed
	GMP status.	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	Me- too could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm.
	Submission by the firm.	Firm has provided LEZAN DRENCH of M/s IZFAAR PHARMACEUTICAL, Reg. No. 095637 as me too for the applied formulation.
	Remarks of the Evaluator PEC-XIII	Current GMP status of the firm could not be confirmed.
	Decision of 307th meeting of Registration Board:	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.
	Remarks of the Evaluator PEC-XIII	
	Decision: Approved with innovator's specifications. **Registration letter will be issued after submission of 7500/- fee for change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
895.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Combimit Drench
	Composition	Each ml contains: Oxyclozanide .....94mg Oxfendazole.....34mg Cobalt sulphate.....3.82mg Sodium selenite.....0.50mg
	Diary No. Date of R & I & fee	Dy.No.443 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled

	Me-too status.	Combiox Drench of M/s Selmore Pharma (Pvt.) Ltd Multan Road Lahore 057004.
	GMP status.	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	On Form- 5, Clozasol Gold Drench brand name is applied while fee- challan is of Combimit Drench.
	Decision of 296th meeting of Registration Board:	Deferred for applied composition as on Form- 5, "Clozasol Gold Drench" brand name is applied while fee- challan is of "Combimit Drench".
	Submission by the firm.	Firm has submitted that brand name Clozasol Gold Drench was mentioned by mistake on form-5 and also provided revised form-5. They further provided undertaking that the same fee slip will not be used for any other product.
	Remarks of the Evaluator PEC-XIII	Current GMP status of the firm could not be confirmed.
	Decision of 307th meeting of Registration Board:	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.
	Remarks of the Evaluator PEC-XIII	
	Decision: Approved with innovator's specifications. **Registration letter will be issued after submission of 7500/- fee for change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
896.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Doximit- C Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate ….....25,00,000 IU Tylosin as Tartrate …….....100mg Doxycycline as Hyclate …….....100mg Bromhexine as HCl …..... .....…5mg
	Diary No. Date of R & I & fee	Dy.No.439 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer
	Pack size & Demanded Price	As per SRO & Decontrolled.
	Me-too status.	Could not be confirmed.
	GMP status.	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	Me- too could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission by the firm.	Firm has provided Doximac-C water soluble powder, Reg. No. 049530, Prix Pharma as me too for the applied formulation.
	Remarks of the Evaluator PEC-XIII	Current GMP status of the firm could not be confirmed.
	Decision of 307th meeting of Registration Board:	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.
	Remarks of the Evaluator PEC-XIII	

	Decision: Approved. The firm will submit the target species of the applied formulation.	
897.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Clozasol Gold Drench
	Composition	Each 100ml contains: Levamisole (HCl)…… …….3gm Oxyclozanide……..6gm Cobalt Sulphate…….0.334gm Sodium Selenite……..…0.1gm
	Diary No. Date of R & I & fee	Dy.No.438 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form.	Form-5.
	Finished product Specification.	Manufacturer
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status.	Could not be confirmed.
	GMP status.	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	On application, following formulation is applied: Each ml contains: Oxfendazole……..94mg Oxyclozanide…….……34mg Cobalt Sulphate……..…3.82mg Sodium Selenite……0.50mg • Me- too status could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for following reasons: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Different compositions have been applied in different parts of dossier.
	Submission by the firm.	Firm has provided Helmex Gold Drench of M/s Selmore Pharma, Reg. No. 057005 as me too for the applied formulation and further submitted that their correct formulation is as under: Each 100ml contains: Levamisole (HCl)…….3gm Oxyclozanide……..……..6gm Cobalt Sulphate…….0.334gm Sodium Selenite……..…0.1gm
	Remarks of the Evaluator PEC-XIII	Current GMP status of the firm could not be confirmed.
	Decision of 307th meeting of Registration Board:	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	• Firm has submitted copy of GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023. • Fee required or not ?
	Remarks of the Evaluator PEC-XIII	
	Decision: Approved with innovator's specifications. **Registration letter will be issued after submission of 30,000/- fee for change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
898.	Name and address of manufacturer/ Applicant	M/s Nawan Laboratories (Pvt.) Ltd., plots No. 136, sector 15, Korangi Industrial Area Karachi (Dry powder sachet section (General) veterinary).
	Brand Name + Dosage Form + Strength	Easy Digest powder.

	Composition	Each 1000gm contains: Propionic Acid Calcium ……..250gm Propionic Acid Sodium ……400gm Acetanilide ……150gm Magnesium Oxide ……..125gm Iron II Sulphate ……..0.400mg Zinc Sulphate ……0.100mg Magnesium Sulphate ……...0.200mg Copper Sulphate ……..0.450mg Cobalt Sulphate ……0.400mg Sodium Molybdate ……0.100mg Sodium Chloride ……20gm
	Diary No. Date of R & I & fee	Dy. No 11444 dated 05-03-2019; Rs.20,000/- dated 04-03-2019.
	Pharmacological Group	Appetizing and digestive tonic powder.
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	100gm sachet & decontrolled.
	Approval status of product in Reference Regulatory Authorities	N/A.
	Me-too status	Alvegest powder, Star Laboratories, Reg. No. 008029.
	GMP status	Firm has submitted routine GMP inspection report dated 25-01-2022 wherein it is concluded that keeping in view the attitude of the management towards continuous improvements and current observations their overall GMP compliance is rated as good.
	Remarks of the Evaluator	• Firm was asked to revise their label claim as per their demanded pack size. They revised their label claim as follows; Each 100-gm powder contains; Propionic Acid Calcium ……..…. 25gm Propionic Acid Sodium ……40gm Acetanilide ……15gm Magnesium Oxide ……12.5gm Iron II Sulphate ……0.040mg Zinc Sulphate ……0.010mg Magnesium Sulphate ……0.020mg Copper Sulphate ……...0.045mg Cobalt Sulphate ……0.040mg Sodium Molybdate ……0.010mg Sodium Chloride ……2gm • Firm has submitted me too details as Alvegest powder manufactured by Star Laboratories, Reg. No. 008029. • *However, the composition of the applied formulation is different from the already approved formulation.*
	Decision of 307th meeting of Registration Board;	Deferred for submission evidence of already approved formulation by the Registration Board with brand name, Registration number & manufacturer name. As the composition of the applied formulation is different from submitted me too in concentration of Iron II Sulphate, Zinc, Magnesium Sulphate, Copper Sulphate, Cobalt Sulphate and Sodium Molybdate.
	Reply by the firm;	Firm has revised their formulation as per available approved/registered me too formulation without

		submission of applicable fee for Change of label claim/formulation. Revised label claim is as under; Each 1000-gm powder contains; Propionic Acid Calcium ……. 250gm Propionic Acid Sodium ……400gm Acetanilide ……150gm Magnesium Oxide ……125gm Iron II Sulphate …… 400mg Zinc Sulphate ……. 100mg Magnesium Sulphate ……. 200mg Copper Sulphate ……..... 450mg Cobalt Sulphate ……. 400mg Sodium Molybdate …… 100mg Sodium Chloride …… 20gm
	Remarks of the Evaluator PEC XIII	Full fee along with new form 5 and master formulation shall be submitted.
	Decision of 324th meeting of Registration Board:	Deferred for following; • Submission of full fee of 30,000/- for correction/pre-approval change in the label claim, method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with revised form 5 shall be submitted. • Evidence of testing facility required for conducting testing of the applied formulation.
	Reply submitted by the firm:	• Firm has submitted 30,000/- fee vide slip no. 999270798078 dated 09-03-2023 along with revised Form 5. • Firm has also submitted a list of 67 equipments in their quality control laboratory mentioning 2 HPLCs, UV spectrophotometer, FTIR, 02 Atomic absorptions and many more.
	Remarks of the Evaluator PEC XIII	
	Decision: Deferred for verification of the testing facility and availability of Atomic absorption spectrophotometer in a panel inspection report. **The board also advised the Division of QA/LT to confirm the availability of required testing facilities of all the manufacturers of such formulations and make it part of GMP inspection reports.**	

Case 08: Registration applications Locally manufactured (Human) drugs New Section/New License cases on Form 5F.

899.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd.,19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.

	Evidence of approval of manufacturing facility	Dry powder injectable (Penicillin). – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8796 dated 30-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0863114487 Dated 14-03-2023.
	The proposed proprietary name / brand name	**Ampiwell 1gm for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ampicillin as Sodium …… 1gm.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin's.
	Pharmaceutical form of applied drug	Powder for injection.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1's (one vial packed with 10ml of WFI).
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Penbritin-S Eq. 1gm base/vial USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Zampicillin Injection 1g, Zafa Pharmaceutical Laboratories, Reg. No. 037826.
	Name and address of API manufacturer.	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (ASS-0422043, mfg. date 04-2022) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time

		conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. ASS-0117001, ASS-0117002 & ASS-0117003.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Ampicillin sodium 500mg for injection, manufactured by Chongquing medicine and health products, batch No. 211028, mfg. date 10-2021 by performing quality test pH, Average weight, water content, assay and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.		
API Lot No.	ASS-0422043.		
Description of Pack (Container closure system)	Glass vial type II with rubber stopper and aluminium flip of seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period.	Real time: 6 months Accelerated: 6 months		
Frequency.	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size .	400 Vials	400 Vials	400 Vials
Manufacturing Date.	07-2022	07-2022	07-2022
Date of Initiation.	30-07-2022	30-07-2022	30-07-2022
No. of Batches.	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. DC/A-I/2020/1517 dated 09-09-2020 issued by Drug Control Organization, Rajasthan, Jaipur. Valid till 11-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. 6893/2022DRAP dated 07-07-2022 mentioning 2kg of Ampicillin Sodium sterile (BP) with batch No. ASS-0422043, mfg. date of 30-04-2022 from M/s

		Vartika Chemicals & Pharmaceuticals Pvt. Ltd., India attested by Assistant Director, I&E, DRAP, Lahore dated 07-06-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Copy of GMP certificate (DC/Mfg-25/E-01761/GMP/2023/4069 dated 06-10-2023) of drug substance manufacturers issue by Food Safety and Drugs Control Commissionerate valid for three years is submitted.
2.	2.3	• Revised table for literature references with correct information regarding the drug substance and finished product with applicable fee shall be submitted.	Firm has submitted revised table for literature references with correct information without submission of fee.
3.	3.2.S.4.1	Specification of the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
4.	3.2.P.2.2	• Justification shall be submitted for not performing pharmaceutical equivalence against the innovator product. • Justification for not performing different tests like identification, BET, particulate matter test etc. in pharmaceutical equivalence studies.	Firm has submitted that innovator pack is not available in market, so we used competitor pack pharmaceutical equivalence as per guidance documents. Firm has submitted new PE studies against comparator product i.e. Amplipen 1gm injection, B. No. AP210103 manufactured by M/s PDH Laboratories. Updated/revised pharmaceutical equivalence report has mentioned all these tests.
5.	3.2.P.5.2	Assay calculation formula in the analytical procedures shall be elaborated. As only formula is given while there is no elaboration of the formula.	Analytical procedures had been updated by incorporating the elaboration of formula for Assay calculation. **Result = (rU/rS) × (Cs/Cu) × P** rU = peak response of Ampicillin from the Sample solution rS = peak response of Ampicillin from the Standard Solution Cs = concentration of Standard Solution RS Cu = concentration of Sample Solution P = Potency of working standard

6.	3.2.P.5.3	Verification studies are for ampicillin trihydrate. Justification shall be submitted.	Firm has submitted method verification studies for Ampicillin sodium.
7.	3.2.P.8	• Raw data sheets for calculation of assay of ampicillin at each time interval with calculation formula shall be submitted. • Justify the injection volume in the submitted chromatograms (20) with respect to submitted analytical procedures and BP monograph where injection volume of 50µl is mentioned. • Justify the submitted chromatograms with respect to BP monograph wherein it is mentioned that "the assay is not valid unless, in the chromatograms obtained with solution (3), the resolution peaks between the peaks due to ampicillin and Cefradine is at least 3.0. if necessary, adjust the composition of the mobile phase to achieve the desired resolution." • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. Firm has submitted that Analytical method is adjusted as per actual practice, in accordance with USP <621> chromatography and system suitability parameters complies the specification. The same had been validated. Firm has submitted that system suitability injection was run separately by preparing the solution with working standard of Ampicillin and Cefradine, it is not used for the calculation of Assay results. They also submitted separate chromatograms. Application approved in different meeting (323, 324) on Form 5F.

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XV

Cases of Form 5-F (Local Manufacturing)

900.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33027: 17-11-2022
	Details of fee submitted	PKR 75,000/- : vide slip no. 6925563892 dated 28-07-2022
	The proposed proprietary name / brand name	Eslicarbazepine 600mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….600mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the copies of drug substance specification and analytical procedure used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm submitted the analytical method verification report of drug substance by drug product manufacturer.
3.	**3.2.P.2.2.1**	Justify for not performing the dissolution test in accordance with innovator product as evident from the results given in pharmaceutical equivalence report. Further, clarify the time point at which the mentioned percentage release of drug has achieved.	Firm amended the acceptance criteria of dissolution test in accordance with innovator product and accordingly submit the revised pharmaceutical equivalence report.
4.	**3.2.P.5.1**	Justify for not adopting the dissolution acceptance criteria in accordance with the innovator product approved in USFDA. Since innovator recommend two point dissolution for Eslicarbazepine acetate tablet, while you have mentioned the single time point acceptance criteria for the applied product.	Firm updated the acceptance criteria of dissolution test in line with innovator product and submit the performance report accordingly.
5.	**3.2.P.8.2**	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of Form 6 indicating that the firm imported eslicarbazepine acetate 10 kg from M/s. CTX Life Science Pvt. Ltd., India.

6.	**3.2.P.8.2**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the copy of GMP certificate of drug substance manufacturer, which is valid till 29/05/2025.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

901.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33026: 17-11-2022
	Details of fee submitted	PKR 75,000/- : vide slip no. 7157393437 dated 28-07-2022
	The proposed proprietary name / brand name	Eslicarbazepine 400mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….400mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the copies of drug substance specification and analytical procedure used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well*	Firm submitted the analytical method verification report of drug substance by drug product manufacturer.

		as non-compendial drug substance(s) shall be submitted".	
3.	**3.2.P.2.2.1**	Justify for not performing the dissolution test in accordance with innovator product as evident from the results given in pharmaceutical equivalence report. Further, clarify the time point at which the mentioned percentage release of drug has achieved.	Firm amended the acceptance criteria of dissolution test in accordance with innovator product and accordingly submit the revised pharmaceutical equivalence report.
4.	**3.2.P.5.1**	Justify for not adopting the dissolution acceptance criteria in accordance with the innovator product approved in USFDA.Since innovator recommend two point dissolution for eslicarbazepine acetate tablet, while you have mentioned the single time point acceptance criteria for the applied product.	Firm updated the acceptance criteria of dissolution test in line with innovator product and submit the performance report accordingly.
5.	**3.2.P.8.2**	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of Form 6 indicating that the firm imported eslicarbazepine acetate 10 kg from M/s. CTX Life Science Pvt. Ltd., India.
6.	**3.2.P.8.2**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the copy of GMP certificate of drug substance manufacturer, which is valid till 29/05/2025.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

902.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33028: 17-11-2022
	Details of fee submitted	PKR 75,000/- : vide slip no.368520189804 dated 28-07-2022
	The proposed proprietary name / brand name	**Eslicarbazepine 800mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….800mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the copies of drug substance specification and analytical procedure used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm submitted the analytical method verification report of drug substance by drug product manufacturer.
3.	**3.2.P.2.2.1**	Justify for not performing the dissolution test in accordance with innovator product as evident from the results given in pharmaceutical equivalence report. Further, clarify the time point at which the mentioned percentage release of drug has achieved.	Firm amended the acceptance criteria of dissolution test in accordance with innovator product and accordingly submit the revised pharmaceutical equivalence report.
4.	**3.2.P.5.1**	Justify for not adopting the dissolution acceptance criteria in accordance with the innovator product approved in USFDA.Since innovator recommend two point dissolution for eslicarbazepine acetate tablet, while you have mentioned the single time point acceptance criteria for the applied product.	Firm updated the acceptance criteria of dissolution test in line with innovator product and submit the performance report accordingly.
5.	**3.2.P.8.2**	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of Form 6 indicating that the firm imported eslicarbazepine acetate 10 kg from M/s. CTX Life Science Pvt. Ltd., India.

6.	**3.2.P.8.2**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the copy of GMP certificate of drug substance manufacturer, which is valid till 29/05/2025.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

903.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.33025 dated : 17-11-2022
	Details of fee submitted	PKR 75,000/- : vide slip no.80579694651 dated 28-07-2022
	The proposed proprietary name / brand name	**Eslicarbazepine 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….200mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the copies of drug substance specification and analytical procedure used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method*	Firm submitted the analytical method verification report of drug substance by drug product manufacturer.

		precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	
3.	**3.2.P.2.2.1**	Justify for not performing the dissolution test in accordance with innovator product as evident from the results given in pharmaceutical equivalence report. Further, clarify the time point at which the mentioned percentage release of drug has achieved.	Firm amended the acceptance criteria of dissolution test in accordance with innovator product and accordingly submit the revised pharmaceutical equivalence report.
4.	**3.2.P.5.1**	Justify for not adopting the dissolution acceptance criteria in accordance with the innovator product approved in USFDA.Since innovator recommend two point dissolution for eslicarbazepine acetate tablet, while you have mentioned the single time point acceptance criteria for the applied product.	Firm updated the acceptance criteria of dissolution test in line with innovator product and submit the performance report accordingly.
5.	**3.2.P.8.2**	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of Form 6 indicating that the firm imported eslicarbazepine acetate 10 kg from M/s. CTX Life Science Pvt. Ltd., India.
6.	**3.2.P.8.2**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the copy of GMP certificate of drug substance manufacturer, which is valid till 29/05/2025.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

904.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s. Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.33024 dated : 17-11-2022
	Details of fee submitted	PKR 75,000/- : vide slip no.38639256086 dated 28-07-2022
	The proposed proprietary name / brand name	**Eslicarbazepine suspension 50mg/ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Eslicarbazepine Acetate….50mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (Zebinix (Eslicarbazepine) Suspension 50mg/ml)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the copies of drug substance specification and analytical procedure used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm submitted the analytical method verification report of drug substance by drug product manufacturer.
3.	**3.2.P.4**	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm submitted the COA of both excipient of propylene glycol and sorbitol including the test results of presence of ethylene glycol and diethylene glycol.
4.	**3.2.P.5.1**	Justify for not including test of dissolution in the specification of finished product since the innovator product recommends dissolution in the specification of suspension.	Firm submitted the updated specification of drug product including the test of dissolution. Further firm submitted the performance report of dissolution test.
5.	**3.2.P.8.2**	• Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by	• Firm submitted the copy of Form 6 indicating that the firm imported eslicarbazepine acetate 10 kg from M/s. CTX Life Science Pvt. Ltd., India. • Firm submitted the copy of GMP certificate of drug substance manufacturer, which is valid till 29/05/2025.

		concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	
6.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

905.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3319 dated : 06-02-2023
	Details of fee submitted	PKR 75,000/- : vide slip no.3914556825 dated 14-12-2022
	The proposed proprietary name / brand name	Tolvaptal 7.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Tolvaptan…..7.5mg
	Pharmacotherapeutic Group of (API)	Vasopressin 2 receptor antagonist (WHO ATC code: C03XA01)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (Zebinix (Eslicarbazepine) Suspension 50mg/ml)
	For generic drugs (me-too status)	NA

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Justify for not adopting the same assay method for verification studies as recommended by the drug substance manufacturer.	Firm replied that "At Kaizen, we've conducted various assay methods, including those provided by the manufacturer and several internationally recognized methods. These methods were assessed using a PDA detector, with changing different parameters such as mobile phase, wavelength, and flow rate.

			Through optimization, we refined these parameters to develop the most effective method. Subsequently, we verified the chosen method according to the required parameters of analytical method verification, confirming its accuracy, precision, and specificity to the analyte. Notably, the developed method yields a distinct and precise analyte peak in the chromatogram. For your evaluation a chromatogram of one standard solution and one sample solution is attached for your review and evaluation".
3.	**3.2.P.2.2.1**	Justify for using 6 units of each reference and test product for CDP instead of 12 units as recommended by Registration Board in its 293rd meeting.	Firm replied that According to the available laboratory records (raw data), it appears that the analyst conducted tests on 12 units. However, due to a lack of a suitable format for calculating data for 12 units, they processed the data using a calculation sheet designed for 6 units. We want to assure you that the results for the remaining 6 units closely identical to those submitted for the initial 6 units. Subsequently, we have recalculated the data incorporating all 12 units, and no significant differences have been noted in the final results. 12 units data sheet are resubmitted.
4.	**3.2.P.5.1**	Justify for not adopting the same acceptance criteria for dissolution test as recommended by the innovator product, since the revealed literature of innovator product recommend separate acceptance criteria for 60mg and lower strength.	Firm replied that "We have established the same acceptance criteria of "Dissolution Time" as recommended by the innovator, which is 30 minutes. In accordance with this, we have performed dissolution testing for the current 18M (Batch No. TF-04) stability studies. Dissolution test report of Tolvaptan 7.5, 15 and 30mg tablet for 18M- LT (Batch No. TF-04 for each strength) are attached".
5.	**3.2.P.5.2**	Justify for performing the dissolution test on UV spectrophotometer, since the innovator product recommends the performance of dissolution test on HPLC.	Firm in their reply stated that "In the method development phase of the product, the analyst conducted UV spectrophotometer tests on a spectrum of Tolvaptan at a concentration of 10 mcg/ml. They observed a distinct peak (max) at 254 nm. Additionally, the absorbance at this wavelength showed linearity across various concentrations. Consequently, we have chosen to adopt the UV spectrophotometer as our testing method.
6.	**3.2.P.5.4**	• Justify for not performing the uniformity of dosage unit test while performing the batch analysis of drug product for 7.5mg and 15mg strength. • Clarify for giving the dissolution results of pregabalin in the batch analysis report of Tolvaptan Tablet.	• Firm replied that Based on the available raw data of 7.5mg & 15mg tablets, the analyst conducted uniformity of dosage unit testing as part of the batch analysis. However, this information was not included in the report due to the unavailability of an option for reporting in the software report format at that time. We have now updated the report

			format to include the uniformity of dosage unit testing results. The new report, which incorporates these test results, is being submitted for your review. • The word pregabalin is written by mistake in the batch analysis report of Tolvaptan tablet. It was Copy of corrected batch.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of all three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

906.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3320 dated : 06-02-2023
	Details of fee submitted	PKR 75,000/- : vide slip no.64921571 dated 14-12-2022
	The proposed proprietary name / brand name	Tolvaptal 15 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Tolvaptan…..15mg
	Pharmacotherapeutic Group of (API)	Vasopressin 2 receptor antagonist (WHO ATC code: C03XA01)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved SAMSCA Tablet 7.5mg
	For generic drugs (me-too status)	NA

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Justify for not adopting the same assay method for verification studies as recommended by the drug substance manufacturer.	Firm replied that "At Kaizen, we've conducted various assay methods, including those provided by the manufacturer and several internationally

			recognized methods. These methods were assessed using a PDA detector, with changing different parameters such as mobile phase, wavelength, and flow rate. Through optimization, we refined these parameters to develop the most effective method. Subsequently, we verified the chosen method according to the required parameters of analytical method verification, confirming its accuracy, precision, and specificity to the analyte. Notably, the developed method yields a distinct and precise analyte peak in the chromatogram. For your evaluation a chromatogram of one standard solution and one sample solution is attached for your review and evaluation".
3.	**3.2.P.2.2.1**	Justify for using 6 units of each reference and test product for CDP instead of 12 units as recommended by Registration Board in its 293rd meeting.	Firm replied that According to the available laboratory records (raw data), it appears that the analyst conducted tests on 12 units. However, due to a lack of a suitable format for calculating data for 12 units, they processed the data using a calculation sheet designed for 6 units. We want to assure you that the results for the remaining 6 units closely identical to those submitted for the initial 6 units. Subsequently, we have recalculated the data incorporating all 12 units, and no significant differences have been noted in the final results. 12 units data sheet are resubmitted.
4.	**3.2.P.5.1**	Justify for not adopting the same acceptance criteria for dissolution test as recommended by the innovator product, since the revealed literature of innovator product recommend separate acceptance criteria for 60mg and lower strength.	Firm replied that "We have established the same acceptance criteria of "Dissolution Time" as recommended by the innovator, which is 30 minutes. In accordance with this, we have performed dissolution testing for the current 18M (Batch No. TF-04) stability studies. Dissolution test report of Tolvaptan 7.5, 15 and 30mg tablet for 18M- LT (Batch No. TF-04 for each strength) are attached".
5.	**3.2.P.5.2**	Justify for performing the dissolution test on UV spectrophotometer, since the innovator product recommends the performance of dissolution test on HPLC.	Firm in their reply stated that "In the method development phase of the product, the analyst conducted UV spectrophotometer tests on a spectrum of Tolvaptan at a concentration of 10 mcg/ml. They observed a distinct peak (max) at 254 nm. Additionally, the absorbance at this wavelength showed linearity across various concentrations. Consequently, we have chosen to adopt the UV spectrophotometer as our testing method.
6.	**3.2.P.5.4**	• Justify for not performing the uniformity of dosage unit test while performing the batch analysis of drug product for 7.5mg and 15mg strength.	• Firm replied that Based on the available raw data of 7.5mg & 15mg tablets, the analyst conducted uniformity of dosage unit testing as part of the batch analysis. However, this information was not

		• Clarify for giving the dissolution results of pregabalin in the batch analysis report of Tolvaptan Tablet.	included in the report due to the unavailability of an option for reporting in the software report format at that time. We have now updated the report format to include the uniformity of dosage unit testing results. The new report, which incorporates these test results, is being submitted for your review. • The word pregabalin is written by mistake in the batch analysis report of Tolvaptan tablet. It was Copy of corrected batch.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of all three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

907.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3321 dated : 06-02-2023
	Details of fee submitted	PKR 75,000/- : vide slip no.90034705620 dated 14-12-2022
	The proposed proprietary name / brand name	Tolvaptal 30 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Tolvaptan…..30mg
	Pharmacotherapeutic Group of (API)	Vasopressin 2 receptor antagonist (WHO ATC code: C03XA01)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved SAMSCA Tablet 15mg,30mg,60mg
	For generic drugs (me-too status)	NA

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug	Firm submitted the Copies of the Drug substance specifications and analytical procedures used for routine testing of the

		substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Drug substance/Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Justify for not adopting the same assay method for verification studies as recommended by the drug substance manufacturer.	Firm replied that "At Kaizen, we've conducted various assay methods, including those provided by the manufacturer and several internationally recognized methods. These methods were assessed using a PDA detector, with changing different parameters such as mobile phase, wavelength, and flow rate. Through optimization, we refined these parameters to develop the most effective method. Subsequently, we verified the chosen method according to the required parameters of analytical method verification, confirming its accuracy, precision, and specificity to the analyte. Notably, the developed method yields a distinct and precise analyte peak in the chromatogram. For your evaluation a chromatogram of one standard solution and one sample solution is attached for your review and evaluation".
3.	**3.2.P.2.2.1**	Justify for using 6 units of each reference and test product for CDP instead of 12 units as recommended by Registration Board in its 293rd meeting.	Firm replied that According to the available laboratory records (raw data), it appears that the analyst conducted tests on 12 units. However, due to a lack of a suitable format for calculating data for 12 units, they processed the data using a calculation sheet designed for 6 units. We want to assure you that the results for the remaining 6 units closely identical to those submitted for the initial 6 units. Subsequently, we have recalculated the data incorporating all 12 units, and no significant differences have been noted in the final results. 12 units data sheet are resubmitted.
4.	**3.2.P.5.1**	Justify for not adopting the same acceptance criteria for dissolution test as recommended by the innovator product, since the revealed literature of innovator product recommend separate acceptance criteria for 60mg and lower strength.	Firm replied that "We have established the same acceptance criteria of "Dissolution Time" as recommended by the innovator, which is 30 minutes. In accordance with this, we have performed dissolution testing for the current 18M (Batch No. TF-04) stability studies. Dissolution test report of Tolvaptan 7.5, 15 and 30mg tablet for 18M- LT (Batch No. TF-04 for each strength) are attached".
5.	**3.2.P.5.2**	Justify for performing the dissolution test on UV spectrophotometer, since the innovator product recommends the performance of dissolution test on HPLC.	Firm in their reply stated that "In the method development phase of the product, the analyst conducted UV spectrophotometer tests on a spectrum of Tolvaptan at a concentration of 10 mcg/ml. They observed a distinct peak (max) at 254 nm. Additionally, the absorbance at this wavelength showed linearity across various concentrations. Consequently, we

			have chosen to adopt the UV spectrophotometer as our testing method.
6.	**3.2.P.5.4**	• Justify for not performing the uniformity of dosage unit test while performing the batch analysis of drug product for 7.5mg and 15mg strength. • Clarify for giving the dissolution results of pregabalin in the batch analysis report of Tolvaptan Tablet.	• Firm replied that Based on the available raw data of 7.5mg & 15mg tablets, the analyst conducted uniformity of dosage unit testing as part of the batch analysis. However, this information was not included in the report due to the unavailability of an option for reporting in the software report format at that time. We have now updated the report format to include the uniformity of dosage unit testing results. The new report, which incorporates these test results, is being submitted for your review. • The word pregabalin is written by mistake in the batch analysis report of Tolvaptan tablet. It was Copy of corrected batch.
7.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of all three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

908.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot no. E-128,E-128 & E-129, North Western Zone, Port Qasim Authority Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3318 dated : 06-02-2023
	Details of fee submitted	PKR 75,000/- : vide slip no.21770243430 dated 14-12-2022
	The proposed proprietary name / brand name	Tolvaptal 1% Granules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Tolvaptan……10mg
	Pharmacotherapeutic Group of (API)	Vasopressin 2 receptor antagonist (WHO ATC code: C03XA01)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1X30's sachet of 10mg packed in plastic jar
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Samsca 1% granules approved in PMDA Japan
	For generic drugs (me-too status)	NA

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Justify for not adopting the same assay method for verification studies as recommended by the drug substance manufacturer.	Firm replied that "At Kaizen, we've conducted various assay methods, including those provided by the manufacturer and several internationally recognized methods. These methods were assessed using a PDA detector, with changing different parameters such as mobile phase, wavelength, and flow rate. Through optimization, we refined these parameters to develop the most effective method. Subsequently, we verified the chosen method according to the required parameters of analytical method verification, confirming its accuracy, precision, and specificity to the analyte. Notably, the developed method yields a distinct and precise analyte peak in the chromatogram. For your evaluation a chromatogram of one standard solution and one sample solution is attached for your review and evaluation".
3.	**3.2.P.2.2.1**	Justify for using 6 units of each reference and test product for CDP instead of 12 units as recommended by Registration Board in its 293rd meeting.	Firm replied that According to the available laboratory records (raw data), it appears that the analyst conducted tests on 12 units. However, due to a lack of a suitable format for calculating data for 12 units, they processed the data using a calculation sheet designed for 6 units. We want to assure you that the results for the remaining 6 units closely identical to those submitted for the initial 6 units. Subsequently, we have recalculated the data incorporating all 12 units, and no significant differences have been noted in the final results. 12 units data sheet are resubmitted.
4.	**3.2.P.5.1**	Justify for not adopting the same acceptance criteria for dissolution test as recommended by the innovator product, since the revealed literature of innovator product recommend separate acceptance criteria for 60mg and lower strength.	Firm replied that "The acceptance criteria for the current product is set at not less than 80% (Q). However, according to the British Pharmacopeia, the minimum acceptance criteria for immediate release dosage forms should be not less than 75% (Q). Through the results of numerous dissolution tests conducted at various time points and RPMs, it was determined that adhering to the NLT 80% limit ensures the discriminatory power of the dissolution test".
5.	**3.2.P.5.2**	Justify for performing the dissolution test on UV spectrophotometer, since the innovator product recommends the performance of dissolution test on HPLC.	Firm replied that "In the method development phase of the product, the analyst conducted UV spectrophotometer tests on a spectrum of Tolvaptan at a concentration of 10 mcg/ml. They observed a distinct peak (max) at 254 nm. Additionally, the absorbance at this wavelength showed linearity across various concentrations.

			Consequently, we have chosen to adopt the UV spectrophotometer as our testing method. Based on the available raw data, the analyst conducted uniformity of dosage unit testing as part of the batch analysis. However, this information was not included in the report due to the unavailability of an option for reporting in the software report format at that time. We have now updated the report format to include the uniformity of dosage unit testing results. The new report, which incorporates these test results, is being submitted for your review".
6.	**3.2.P.7**	Please specify the reference of sachet packing of granules since the innovator literature revealed that the samsca 1% granule is marketed in 30g plastic without any hint of sachet packaging.	Firm clarified that "30g of Tolvaptan 1% granules were filled into plastic jars, and stability testing was conducted in this packaging. The summary sheets mistakenly mentioned sachets. The corrected summary sheets are attached for your review". Firm corrected that 10mg of granules filled in sachet and 30 sachet filled in plastic jar.
7.	**3.2.P.8.2**	Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches.	Firm submitted the commercial invoice attested by DRAP dated 02-12-2020.
8.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Firm submitted the BMR of all three trial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

909.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3315 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.5069866666 dated 09-01-2023
	The proposed proprietary name / brand name	Neprival 24mg/26mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….24mg Valsartan…..26mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 24/26mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 093098)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.
5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.
6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.
9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

910.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3316 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.243624158 dated 13-01-2023
	The proposed proprietary name / brand name	Neprival 49mg/51mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….49mg Valsartan…..51mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 49/51mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 093083)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.
5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.
6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.
9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the

		composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

911.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3317 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.50178601519 dated 13-01-2023
	The proposed proprietary name / brand name	Neprival 97mg/103mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….97mg Valsartan…..103mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 97/103mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 103096)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.
5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.

6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.
9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

912.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.474 dated : 05-01-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.31737402255 dated 03-01-2023
	The proposed proprietary name / brand name	Cmyate 2MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 2MIU eq. to colistimethate Sodium….160mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (1MIU & 2MIU)
	For generic drugs (me-too status)	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration

	sodium instead of Colistimethate base activity as recommended by USP.	letter of cmyate IMIU Injection is as attached). However, the Assay results were calculated as Colistine base activity as defined in USP. But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during manufacturing, since, the drug substance is used in the preparation of injectable dosage form.	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is sensitive to heat so heat sterilization of the product is not suitable."
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays*, specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range".* then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin"

		The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity. However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
7.	• Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA). • Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
8.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm replied that "Comparative study was performed with the following product: Product name: Colistim Injection By M/s Biopharmaceutica".
9.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
10.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"
11.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.
12.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.

13.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Not submitted the reply of this query.
14.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
15.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".
16.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
17.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision: Deferred for submission of following:

- **Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.**
- **Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.**
- **Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".**
- **Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.**
- **Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.**

- **How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".**
- **Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.**
- **Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.**

913.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.1554 dated : 17-01-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.0564003397 dated 12-01-2023
	The proposed proprietary name / brand name	Cmyate 3MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 3MIU eq. to colistimethate Sodium….240mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (1MIU & 2MIU)
	For generic drugs (me-too status)	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration letter of cmyate IMIU Injection is as attached). However, the Assay results were calculated as Colistine base activity as defined in USP. But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during manufacturing, since, the drug	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is sensitive to heat so heat sterilization of the product is not suitable."

	substance is used in the preparation of injectable dosage form.	
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays*, specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range".* then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin" The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity. However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
7.	• Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA). • Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).

8.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm replied that "Comparative study was performed with the following product: Product name: Colistim Injection By M/s Biopharmaceutica".
9.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
10.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"
11.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 μg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.
12.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.
13.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the	Not submitted the reply of this query.

	general chapter "Antibiotics Microbial Assays <81>".	
14.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
15.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".
16.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
17.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision: Deffered for the submission of following:

- **Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.**
- **Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.**
- **Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".**
- **Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.**
- **Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.**
- **How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".**
- **Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.**
- **Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.**

914.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3223 dated : 03-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.7878225619 dated 01-02-2023
	The proposed proprietary name / brand name	Cmyate 4.5 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 4.5MIU eq. to colistimethate Sodium….360mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Coly-Mycin® M Parenteral 150 mg colistin base activity **USFDA** Approved
	For generic drugs (me-too status)	Colistim 4.5MIU by Biocare Pharmaceutica,

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration letter of cmyate IMIU Injection is as attached). However, the Assay results were calculated as Colistine base activity as defined in USP. But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during manufacturing, since, the drug substance is used in the preparation of injectable dosage form.	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is sensitive to heat so heat sterilization of the product is not suitable."
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays*, specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the*

		linear range". then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Description of applied product is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied product is white to slightly yellow powder, clarify how the applied product is similar to innovator product/reference product.	Firm has not submitted the reply of this query.
7.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin" The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity. However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
8.	Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium

		against the determined potency in terms of Colistimethate base activity (CBA).
9.	Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial i.e. 360mg of colistimethate sodium.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
10.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm submitted the details.
11.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
12.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"
13.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.

14.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.
15.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Not submitted the reply of this query.
16.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
17.	Clarify on which batches you have performed in-use stability studies in the year 2021, because the trail batches on which stability study has been performed were manufactured in 01-2022.	Firm replied that it was a typographic mistake , in-use stability was performed on the same stability batches.
18.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".
19.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
20.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision: Deffered for the submission of following:

- **Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.**
- **Description of applied product is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied product is white to slightly yellow powder, clarify how the applied product is similar to innovator product/reference product.**
- **Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.**
- **Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".**

- **Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.**
- **Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.**
- **How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".**
- **Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.**
- **Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.**

915.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. News Pharma, Plot no. 42, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	**M/s. News Pharma, Plot no. 42, Sunder Industrial Estate, Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.38000 dated : 27-12-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.5822320176 dated 21-12-2022
	The proposed proprietary name / brand name	News-Levo 2.5mg/5ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml oral solution contains: Levocetirizine Dihydrochloride……2.5mg
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (**XYZAL Oral solution)**
	For generic drugs (me-too status)	T-day 0.5mg/ml Syrup of GSK Healthcare.

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.1-3.2.S.4.2**	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug Substance manufacturer. • Justify for adopting the different acceptance criteria for enantiomeric purity test from that recommended in USP monograph of Levocetirizine dihydrochloride.
2.	**3.2.S.4.3**	Please provide complete details of conc. of sample and standard solution along with the chromatographic conditions adopted for the verification of assay method.
3.	**3.2.P.2.5**	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
4.	**3.2.P.2.2.1**	Justify for not including the test of pH and microbial content test while performing the pharmaceutical equivalence of applied product against reference product.

5.	**3.2.P.4**	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
6.	**3.2.P.5.1**	• Justify for not including the test of pH and microbial content in the specification of drug product as recommended for oral solution in the USP general chapter <2> *oral drug products—product quality tests.* • Storage condition mentioned in the specification table is between 2°C-25°C, Justify the storage condition in the light of recommended condition by the innovator product in which excursions permitted to 15°C to 30°C.
7.	**3.2.P.5.2**	Provide reference / scientific rationality for keeping the conc. of sample high in comparison to conc. of standard solution.
8.	**3.2.P.5.4**	Assay procedure given in section 3.2.P.5.2 mentioned that the percentage of levocetirizine dihydrochloride has been calculated while the assay results in batch analysis report stated that the content of Levocetirizine has quantified, clarification is required in this regard.
9.	**3.2.P.7**	Please rationalize the use of pet bottles as the primary container for applied product, since the product is light sensitive.
10.	**3.2.P.8.2**	• As per the analytical method validation report of the drug product, the average area of standard solution at 100% concentration is 1158147 while as per the stability study data the average area of standard solution using the same method is 231909. Justify how this significant difference in peak area can exist during the same analysis using similar methods and how the analytical method can be considered verified. • Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

916.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. News Pharma, Plot no. 42, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	**M/s. News Pharma, Plot no. 42, Sunder Industrial Estate, Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.38211 dated : 28-12-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.7039773156 dated 17-12-2022
	The proposed proprietary name / brand name	News-Lor 5mg/5ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Syrup contains: Loratadine……5mg
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Lorel Syrup 5mg/5ml of M/s.Standpharm Lahore (Reg.no.020951)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug Substance manufacturer.
2.	**3.2.S.4.3**	Please provide complete details of conc. of sample and standard solution along with the chromatographic conditions adopted for the verification of assay method.
3.	**3.2.P.2.5**	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
4.	**3.2.P.4**	Submit the analysis report/COA of excipients propylene glycol and glycerin which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
5.	**3.2.P.5.1**	Justify for not including the test of microbial enumeration tests and tests for specified microorganisms in the specification of drug product as recommended in the USP monograph of Loratadine oral solution.
6.	**3.2.P.8.2**	• As per the analytical method verification report of the drug product, the average area of standard solution at 100% concentration is 900564.5 while as per the stability study data the average area of standard solution using the same method is 181596.7. Justify how this significant difference in peak area can exist during the same analysis using similar methods and how the analytical method can be considered verified. • USP specifies tailing factor NMT 1.6 for loratadine in the system suitability requirements, while the tailing factor values obtained in your chromatograms of drug product show results greater than 1.6. Justify how the test was performed without complying the system suitability requirements as per USP monograph. • Justify why system suitability testing using butyl paraben is not performed as per the method specified in USP. • Rationalize the weight of standard and weight of sample using while calculation of percentage of content of loratadine in comparison of assay procedure given in section 3.2. P.5.2. • Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

917.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	**M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.39373 dated : 29-12-2022
	Details of fee submitted	PKR 30,000/- : vide slip no.48397659956 dated 20-10-2022
	The proposed proprietary name / brand name	SEROFAAS 12.5mg CR Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric film coated controlled release tablet contains: Paroxetine (as Hydrochloride Hemihydrate)….12.5mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors

	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Paxil CR Tablet)
	For generic drugs (me-too status)	Pariz Tablets 12.5mg Reg. No. 052593 M/s Scotmann Pharmaceuticals Islamabad.

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.5**	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.
2.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
3.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	**3.2.S.5**	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
5.	**3.2.P.5.3**	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.
6.	**3.2.P.5.4**	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".
7.	**3.2.P.6**	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	**3.2.P.8.2**	• Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test. • Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP. • Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.
9.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

918.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	**M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.39374 dated : 29-12-2022
	Details of fee submitted	PKR 30,000/- : vide slip no. 38329361038 dated 20-10-2022
	The proposed proprietary name / brand name	SEROFAAS 25mg CR Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric film coated controlled release tablet contains: Paroxetine (as Hydrochloride Hemihydrate)….25mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Paxil CR Tablet)
	For generic drugs (me-too status)	Paraxyl Tablet by CCL Pharmaceuticals

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.5**	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.
2.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
3.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	**3.2.S.5**	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
5.	**3.2.P.5.3**	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.
6.	**3.2.P.5.4**	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".
7.	**3.2.P.6**	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	**3.2.P.8.2**	• Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test. • Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP. • Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.
9.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

919.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.37077 dated : 20-12-2022

	Details of fee submitted	PKR 30,000/- : vide slip no.7626939893 dated 12-12-2022
	The proposed proprietary name / brand name	Haemic Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Tranexamic Acid……500mg
	Pharmacotherapeutic Group of (API)	AntiFibrinolytic agent, Haemostasis
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Traumax 500mg Tablet of M/s. Siza International (Pvt.) Ltd. (Reg.no.024787)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
2.	**3.2.P.5.1**	Adapt the acceptance limit of dissolution in term of Q, since the USP monograph specify the limit with Q value i.e. NLT 80% (Q) of the labeled amount of tranexamic acid dissolved.
3.	**3.2.P.5.2**	Justify how USP specification be applied on the strength of 500mg tablet considering the sample preparation procedure of assay recommended in USP monograph of Tranexamic acid tablet in which crushed powder of tablet equivalent to 650mg tranexamic acid is taken for sample preparation.
4.	**3.2.P.5.3**	Rationalize the spiked concentration of active taken while performing the accuracy parameter of verification studies of drug product specifically with reference to the applied strength.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

920.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Welwrd Pharmaceuticals Plot no. 3, Block A, Phase-I & II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	**M/s. Welwrd Pharmaceuticals Plot no. 3, Block A, Phase-I & II, Industrial Estate, Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3142 dated : 02-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.600962923071 dated 22-09-2022
	The proposed proprietary name / brand name	Pirfona 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Pirfenidone……200mg
	Pharmacotherapeutic Group of (API)	Pyridones
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA Japan (Pirfenidone 200mg tablet) Approved
	For generic drugs (me-too status)	Pirfenox 200mg Tablet of M/s. Highnoon Laboratories.
	Reference to Finished product specifications	Innovator's specification

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.P.2.2.1**	Submit details of manufacturer of reference /comparator product against which pharmaceutical equivalence has been performed.	Firm replied that Pharmaceutical equivalence and CDP has been performed against the comparator product Pirfenox 200mg Tablet batch no. 212755 Mfg date: 09/2021, Exp date: 09/2023 Manufactured by Highnoon Laboratories.
2.	**3.2.P.8.2**	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of Form -6 of import of API Pirfenidone from manufacturer M/s. Optimus Drugs Private Limited, India.
3.	**3.2.P.8.2**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
4.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

921.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ophth Pharma Pvt. Ltd. Plot no. 241, sector 24, Korangi Indutrial Estate, Karachi**
	Name, address of Manufacturing site.	**M/s. Ophth Pharma Pvt. Ltd. Plot no. 241, sector 24, Korangi Indutrial Estate, Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.45/2021-DRAP(K) dated 29-09-2021.
	Evidence of approval of manufacturing facility	Firm submitted grant of RENEWAL OF DML letter dated 07th June,2022 mentioning Topical Cream section (General) in the approved section list.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.28657 dated 10th October,2022
	Details of fee submitted	Rs.30,000/- vide slip no. 5754259656 dated 16-09-2022
	The proposed proprietary name / brand name	**FUNGICID Topical Cream**
	Strength / concentration of drug of	Terbinafine HCl……1.0%

	Active Pharmaceutical ingredient (API) per unit	
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	Topical Cream
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA (Lamisil Cream)
	For generic drugs (me-too status)	Lamisil Cream of GSK,Karachi
	Name and address of API manufacturer.	Synergene Active Ingredients Pvt. Ltd. Flat no. 402,BhanuEnclave, SundaNagar,Erragadda,Hyderabad,India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted the pharmaceutical equivalence report performed against the Lamisil Topical Cream of GSK Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Synergene Active Ingredients Pvt. Ltd. Flat no. 402,BhanuEnclave, SundaNagar,Erragadda,Hyderabad,India
API Lot No.	NA
Description of Pack (Container closure system)	Aluminium Tube (10g)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12,18,24 (Months)		
Batch No.	**TB-101**	**TB-102**	**TB-103**
Batch Size	1KG	1KG	1KG
Manufacturing Date	08-2019	08-2019	08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr.no.	Section	Observations
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both drug product manufacturer and drug substance manufacturer .
2.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug product instead of drug substance.
3.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
4.	3.2.P.2.2.1	Justify for not performing all the quality parameters mentioned in the specification of drug product while performing the pharmaceutical equivalence.
5.	3.2.P.4	Submit the analysis report/COA of excipients ethylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.
6.	3.2.P.5.1	Justify for not including Microbial Enumeration Tests, Test for specified microorganism and antimicrobial preservative content test in the specification of drug product.

7.	3.2.P.5.3	Justify for not performing the validation studies on the same assay procedure given in section 3.2.P.5.2.
8.	3.2.P.5.4	Justify for not including the test of pH, Microbial Enumeration Tests, Test for specified microorganism and antimicrobial preservative content test in the batch analysis report of drug product.
9.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.
10.	3.2.P.8	• Raw data sheet of stability batches indicates that the adopted assay method was not in accordance with the assay method given in section 3.2.P.5.1, clarification is required in this regard. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
11.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

922.	Name, address of Applicant / Marketing Authorization Holder	M/s High-Q Pharmaceuticals.
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals. Plot No.224 & 225/1 Sector 23, Korangi Industrial Area, Karachi-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29840 dated 21-10-2022
	Details of fee submitted	PKR 30,000/-: dated 06-10-2022 vide slip no. 2842181215
	The proposed proprietary name / brand name	Daytef 600mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 600mg Ceftaroline fosamil (equivalent to 668mg of ceftaroline fosamil monoacetate monohydrate) powder for intravenous infusion
	Pharmaceutical form of applied drug	Yellow white to light yellow powder for intravenous infusion
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 600mg/vial for Injection, USFDA Approved.
	For generic drugs (me-too status)	Not applicable since the product is New drug
	GMP status of the Finished product manufacturer	GMP issuance date: 21st Dec, 2021

		Dry Powder Injectable (Cephalosporin) section is approved
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, PC-250105 Jinan, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Ceftaroline fosamil is not present in any monograph. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (60001EJ87Z-A, 60002EJ87Z-A, 60003EJ87Z-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, force degradation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Teflaro 600mg/vial for Injection by performing quality tests (Identification, Assay, completeness & clarity of solution, Particulate matter, pH, Water content, Fill weight variation, Related substances, bacterial endotoxin and Sterility test.) CDP is not applicable
	Analytical method validation/verification of product	Method validation studies are submitted including linearity, accuracy, precision, LOD, LOQ, Robustness and Force degradation studies

STABILITY STUDY DATA	
Manufacturer of API	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, PC-250105 Jinan, Shandong Province, China
API Lot No.	1002DJ87ZA
Description of Pack (Container closure system)	Clear glass vial plugged with rubber stopper and secured with Aluminium seal (1's) packed in unit carton along with Water for Injection as diluent and leaflet

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	6DTFPD01/22	6DTFPD02/22	6DTFPD03/22
Batch Size	312 vials	312 vials	312 vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	29-03-2022	29-03-2022	29-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Inspection dated 12th July, 2018 for verification of authenticity of stability data of Vesoft 400mg/100mg tablet (Approved in 284th meeting minute of Registration Board)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20170569 issued by Shandong Food & Drug Administration valid till 25/06/2023. According to the latest Drug Administration Law of the People's Republic of China, GMP certification program for all the Chinese pharmaceutical manufacturers is cancelled and won't be issued since Dec 1st, 2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form 6 license No. 2556/21, DRAP/K dated 13/8/2021 is submitted wherein the permission to import for the purpose of test/analysis and stability studies is granted. Commercial Invoice No.A21176J attested by AD I&E DRAP, Karachi dated: 13th Aug, 2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

- CAS NO. of starting material used in the applied product is 229016-73-3 i.e. sterile ceftaroline fosamil monoacetate
- CAS no. of starting material used in the manufacturing of innovator brand is 866021-48-9 i.e. Ceftaroline Fosamil monoacetate monohydrate with the statement that Ceftaroline Fosamil is not stable in the anhydrous form

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit differential fee for the registration of applied new drug product as per the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA dated 7th May 2021.	Firm submitted the differential fee of Rs. 45,000/- vide challan no. 4428087215 dated 09-01-2023.

2. **According to the review literature of innovator brand salt form of drug substance is ceftaroline fosamil acetic acid solvate monohydrate, while the drug substance used in the applied drug product is ceftaroline fosamil monoacetate as per the information submitted in substance part. Justification is required for variation in the drug substance against the innovator product.**

Following points are submitted for your consideration please:

1. Ceftaroline fosamil as starting material:

a. Ceftaroline fosamil monoacetate monohydrate is not a starting material rather it is formulated through chemical transformation of the starting material "Ceftaroline fosamil". The CAS number (229016-73-3) mentioned in the DMF attributes to the starting material i.e., "Ceftaroline fosamil" and the same has also been mentioned in the US FDA Chemistry review document for innovator product. While the CAS no. 866021-48-9 is for the intermediate product Ceftaroline fosamil monoacetate monohydrate, formulated subsequently.

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

A) CAS : 229016-73-3

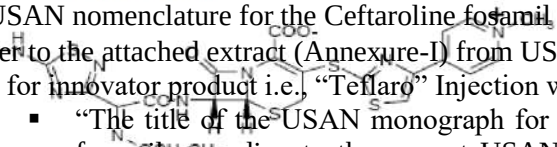
USAN: Ceftaroline Fosamil

(6R,7R)-7-{(2Z)-2-(ethoxyimino)-2-[5-(phosphonoamino)-1,2,4-thiadiazol-3-yl]acetamido}-3-{[4-(1-methylpyridin-1-ium-4-yl)-1,3-thiazol-2-yl]sulfanyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Molecular weight 684.68

Formula $C_{26}H_{21}N_8O_8PS_4$

Structural Formula:



2. Revised USAN nomenclature for the Ceftaroline fosamil monoacetate:

- Please refer to the attached extract (Annexure-I) from US FDA Chemistry review document for innovator product i.e., "Teflaro" Injection which states as under:
  - "The title of the USAN monograph for this drug substance is Ceftaroline fosamil according to the current USAN dictionary online (8/30/10). The USAN monograph currently lists as the chemical name the monoacetate monohydrate (Structure B). The Ceftaroline Fosamil USAN monograph may be changed in the future to show instead the chemical name and Structure A".
- Structure A refers to the title and molecular structure of "Ceftaroline Fosamil" having CAS no. 229016-73-3.
- Also in the most recent editions of USAN (United State Adopted Name) the nomenclature for Ceftaroline fosamil acetate has been revised and is adopted as "Ceftaroline Fosamil" with CAS no. 229016-73-3.
- Based upon above cited facts the nomenclature and CAS number 229016-73-3 for Ceftaroline fosamil has been mentioned in the submitted DMF from Qilu antibiotics.

3. Monohydrate monoacetate form of Ceftaroline Fosamil:
   - As submitted in above points that Ceftaroline fosamil monoacetate monohydrate is formulated as intermediate between starting material "Ceftaroline fosamil" and "Sterile Ceftaroline fosamil with arginine". Qilu antibiotics also process the starting material in the same manner as per innovator product wherein Ceftaroline fosamil is converted to Ceftaroline Fosamil monoacetate solvate (hydrate form) through reaction with acetic acid and glacial WFI (extract of DMF presented below). It is pertinent to mention that the monoacetate form is a solvate hydrate wherein water molecule is available as water of crystallization and hence it was not separately mentioned in the nomenclature of the Intermediate form, whereas it is evident form the Manufacturing outline and Drug substance specifications that "Ceftaroline fosamil monoacetate" contains water.
   - The limit of water content of $\leq$ 3.0% also makes it evident that water content equivalent to about monohydrate form is available in the drug substance.

4. Approval of DMF of Qilu antibiotics by US FDA for the ANDA applications:
   a. It is pertinent to mention that the same DMF of same drug substance titled as "STERILE CEFTAROLINE FOSAMIL WITH ARGININE" has been approved by US FDA as Type –II DMF that has passed the completeness assessment and are available for reference by ANDAs, meaning by that the submitted DMF is acceptable

	to be presented along with any ANDA (generic application) to be filed for the "Ceftaroline Fosamil Injection". DMF No.: 28245. Status: Active. Ref: Types of Drug Master Files (DMFs) | FDA	
3.	Submit stability data of drug substance as per zone-IV-A condition OR In case where the real time stability data of drug substance is not conducted at zone IV-A conditions (e.g 30°C ± 2°C/65% RH ± 5% RH), the drug product manufacturer shall have to submit long term stability studies data of the product for 6 months along with degradation studies in the finished pharmaceutical product.	Firm in their reply submit the validation report of forced degradation studies of finished pharmaceutical product.
4.	Justify for not including the test of Constitution Time and extractable volume test in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm replied that Since we do not have access to innovation's specification, therefore we have performed universal tests (related to dry powder injection) and some specific tests on the finished product. However, considering the importance of these two tests (constitution time & extractable volume), we have performed the tests on retention samples of trial batches of Daytef 400 mg Injection to know the compliance level of our product in comparison with the innovator's product. The results are attached. We have also included these tests in the following documents: Specification and Testing Methods of Daytef 400 mg Injection • Stability Protocol for Commercial batches • Certificate of Analysis format for Finished Product Copies of revised documents, as above, enclosed for your reference.
5.	Elaborate the calculation formula for determination of potency of ceftaroline fosamil.	Firm submitted the following calculation formula: Calculation formula as provided in Doc # API/STM-093 (Raw Material Specification and Control methods): % of Ceftaroline Fosamil in the sample=(ru/rs) x (Cs/Cu) x P Where: ru= Peak area of sample solution rs= Peak area of standard solution Cu= Concentration of sample solution in mg/ml $= \frac{\text{Weight of sample}}{\text{Dilution (100 ml)}} \times \frac{10}{100}$ Cs= Concentration of working standard in mg/ml $= \frac{\text{Weight of standard (Ceftaroline fosamil)}}{\text{Dilution (100 ml)}}$ P= Potency of Ceftaroline Fosamil working standard = Taken from the respective CoA from the supplier $(ru/rs) = \frac{\text{Peak area of Sample}}{\text{Peak area of Standard}}$

6.	Justify, how ceftaroline fosamil separately eluted using the reference standard of ceftaroline fosamil with arginine.	Firm replied that "Prior to analyzing API mix (Ceftaroline fosamil monoacetate monohydrate + L-arginine) we had run working standard of Ceftaroline fosamil and Reference standard of L-Arginine separately, following exactly the same method as to be used for API mix analysis, in order to identify the peaks and to ensure proper resolution (Certificate of Analysis of both these standards are enclosed in Annexure 3). As you would see from the chromatograms of API mix and the reference standard; the peak due to Ceftaroline fosamil and L-arginine are completely separate and reproducible.
7.	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submit the stability data of drug product till 6 month.
8.	Justify the dispensed quantity of ceftaroline fosamil injection with respect to the potency of active.	Firm replied that Ceftaroline fosamil with L-arginine is received as sterile powder, in ready to fill form, therefore the sealed container, of known net weight, is dispensed as such to maintain the sterility. The potency of ceftaroline fosamil is adjusted while calculating the fill weight of powder in vials. % Potency of Ceftaroline fosamil (as monoacetate, monohydrate) = _____% Factor (Ceftaroline fosamil to Ceftaroline fosamil monoacetate monohydrate) = 1.114* Label Claim = Ceftaroline fosamil 400 mg (as Ceftaroline fosamil monoacetate monohydrate) and 264 mg L-arginine per vial Target Fill Weight (Ceftaroline fosamil monoacetate monohydrate) = Label claim x F x 100 / % Potency of Ceftaroline fosamil = 400 x 1.114 x 100 / % Potency of Ceftaroline fosamil = _____ mg/vial (A) Total Fill Weight (Ceftaroline fosamil monoacetate monohydrate + L-arginine) = A + 264 mg = _____ mg / vial * calculated from the molecular weights of Ceftaroline fosamil and Ceftaroline fosamil monoacetate monohydrate: Molecular weight of ceftaroline fosamil monoacetate monohydrate =762.8 Molecular weight of ceftaroline fosamil = 684.7 or 1 mg of ceftaroline fosamil = 1.114 mg of ceftaroline fosamil monoacetate monohydrate

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

923.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. News Pharma Plot No. 42, Sunder Industrial Estate, Lahore.**

	Name, address of Manufacturing site.	M/s. News Pharma Plot No. 42, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.146/2018-DRAP (AD-612094-790) dated 28-08-2018.
	Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter (new section) dated 12th November,2021 of Oral Liquid section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.30591 dated 28th October,2022
	Details of fee submitted	Rs.30,000/- vide slip no. 162005797 dated 19-10-2022
	The proposed proprietary name / brand name	**New-Sacride Syrup 100mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Syrup containing: Iron Polysaccharide 217.4mg eq. to elemental Iron….100mg
	Pharmacotherapeutic Group of (API)	Iron Supplement
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Ironone Syrup of M/s. Novamed Pharmaceuticals (Pvt.) Ltd. Reg.no. 097534
	Name and address of API manufacturer.	Chemiworld Private Limited Plot no. 97, J-Industrial Estate Jamrud, Peshawar.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months.

		The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted the pharmaceutical equivalence report.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Chemiworld Private Limited Plot no. 97, J-Industrial Estate Jamrud, Peshawar.		
API Lot No.	NA		
Description of Pack (Container closure system)	Black color Suspension filled in amber color bottles		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**T-01**	**T-02**	**T-03**
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	10/2021.	10/2021.	10/2021.
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (Date of issue:w.e.f. 19-07-2017) of API manufacturer which was expired in 2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of invoice.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr.no.	Section	Observations	Response of the Firm

1.	**1.5.9**	As per the decision of Registration Board in its 295th meeting related to the Vitamin-Mineral Formulation, "*If any ingredient in the vitamin and mineral formulation is above UL, then it may allow only, if it is available in already defined Reference Regulatory Agencies, for intended therapeutic purpose, otherwise the Firm has to revise its formulation. Furthermore, single ingredient vitamins for certain disease conditions may be registered with therapeutic claim as per approved Reference Regulatory Agencies*". In compliance of this point, please provide the evidence of availability of applied formulation in already defined Reference Regulatory Agencies, since the quantity of iron in applied formulation is above UL Limit.	Firm submitted the international reference of capsule , while the applied product is suspension, further submitted reference neither have same composition as that of applied product nor verifiable from the official website of USFDA.

Decision: Deferred for submission of evidence of availability of applied formulation in already defined Reference Regulatory Agencies, since the quantity of iron in applied formulation is above UL Limit.

924.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore.** **DML No. 000782.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore.** **DML No. 000782.**
	GMP status of the manufacturer	Copy of GMP certificate No. 37/2022-DRAP (AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 30843 dated 31-10-2022 Rs.30,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**APLAST 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apremilast 10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32

	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size & Unit price	Two weeks' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets 28 days' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets.
	The status in reference regulatory authorities	OTEZLA 20 MG FILM-COATED TABLETS, OTEZLA 10 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A- 80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist- Pune Zone 4, Maharashtra India.
	Evaluation by PEC:	
	The applied product has already been approved by Registration Board in its 333rd meeting in which above applicant is contract acceptor/Manufacturer and M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052) is contract giver, based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052) Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Pslot no. 33, Sunder Industrial Estate Lahore. DML No. 000782. Brand Name: APLAST 10mg Tablet	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
925.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.**
	GMP status of the manufacturer	Copy of GMP certificate No. 37/2022-DRAP (AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 30842 dated 31-10-2022 Rs.30,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**APLAST 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apremilast 20mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size & Unit price	Two weeks' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets 28 days' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets.
	The status in reference regulatory authorities	OTEZLA 20 MG FILM-COATED TABLETS, OTEZLA 10 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A- 80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist- Pune Zone 4, Maharashtra India.
	Evaluation by PEC:	
	The applied product has already been approved by Registration Board in its 333rd meeting in which above applicant is contract acceptor/Manufacturer and M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052) is contract giver, based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
Brand Name	APLAST 20mg Tablet

	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
926.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore.** **DML No. 000782.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore.** **DML No. 000782.**

	GMP status of the manufacturer	Copy of GMP certificate No. 37/2022-DRAP (AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 30841 dated 31-10-2022 Rs.30,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**APLAST 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apremilast 30mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size & Unit price	Two weeks' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets 28 days' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets.
	The status in reference regulatory authorities	Otezla 30 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A- 80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist- Pune Zone 4, Maharashtra India.

Evaluation by PEC:

The applied product has already been approved by Registration Board in its 333rd meeting in which above applicant is contract acceptor/Manufacturer and M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052) is contract giver, based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s CCL Pharmaceutical (Pvt.) Ltd. 62- Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
Brand Name	APLAST 30mg Tablet

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

	• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Cases of Form 5-F (Finished Import)

927	**Name, address of Applicant / Importer**	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road Karachi
	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road Karachi **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564,Greece
	Name, address of manufacturer(s)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS 61st km National Road Athens-Lamia, Schimatari Viotias 32009, Greece
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **original**, legalized CoPP certificate (53850) dated 01-10-2021 issued by National Organization of Medicine for Casglo Powder for concentrate for solution of infusion 50mg/vial. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodicity of routine inspection 3 years. **GMP Certificate:** Firm has submitted GMP Certificate No.:8652/23-02-2021 dated 29-0302021 issued by National Organization for Medicine, Greece. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original, legalized Agency Agreement from Meraki Global PTE Ltd. 20 Collyer Quay #11-05, Singapore. The supply and distribution agreement letter specifies that MERAKI is the supplier of pharmaceutical preparations and Hakimsons involve in the business off distribution, sub distrbutors of pharmaceutical product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 4970 Dated:22-02-2022
	Details of fee submitted	PKR 150,000/ Dated: 08-02-2022

	The proposed proprietary name / brand name	Casglo Powder for concentrate for solution of infusion 50mg/vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 50mg Caspofungin (as acetate) After reconstitution in 10.5ml of water for injection, 1ml of concentrate contains 5.2mg Caspofungin.
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Antimycotic for systemic use, ATC code J02AX04
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x50mg Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved) **CANCIDAS CASPOFUNGIN ACETATE**.
	For generic drugs (me-too status)	Caspogin Powder for concentrate for solution of infusion 50mg/vial of M/s. AJM Pharma Pvt. Ltd. (Reg.no. 106828)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Teva API India Private Limited Manufacturing Site: Gajraula site Plot Nos, A-2, A-2/1, A-2/2, UPSIDC Industrial Area, Bijnor Road, Distt. Amroha Gajraula -244 235 (Uttar Pradesh), India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Forced Degradation Studies
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated and real time stability data are conducted at (-18°C±3°C) and (-70°C±5°C) respectively. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the innovator product German Product Cancidas 50mg Merck Sharp & Dhome Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I clear glass vial closed by bromobutyl stoppers. Closed vials are secured by aluminum seal with a plastic flip-off caps.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 4 Three batches of 6500 mL batch size production were tested: 18E032, 18E108 and 18F262 – inverted and upright position. The accelerated stability study data is conducted at 25°C±2°C/60%±5% RH for 6 months. The real time stability study data is conducted at 2-8 °C for 24 months.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid drug sale license of M/s. Hakimson Impex Pvt. Ltd, Karachi.	Firm submitted the valid DSL of applicant which is valid till 19/07/2028.
2.	Submit valid GMP certificate of Manufacturer Abroad ,since the submitted certificate was expired in 2021.	Firm submitted the GMP certificate which was based on inspection conducted on 22-03-2019,issue dated 29-03-2021 and validity was for three years.
3.	Submit legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.	Not submitted.
4.	Submit analytical method verification report of drug substance performed by drug product manufacturer, in accordance with the requirement mentioned in the CTD guidance document approved by Registration Board.	Firm submitted the method transfer for the analytical methods of assay determination, related substances determinations and residual solvents test of Caspofungin Acetate API which are to be transferred from TEVA Laboratories to Anfarm.
5.	Justify the stability conditions adopted for stability studies of drug substance in camparison of stability conditions recommended by innovator product for the drug substance.	Firm replied that they adopted the reference of innovator product approved in USFDA i.e. Cancidas Powder for concentrate for solution of infusion 50mg/vial. According to the review document of innovator brand storage condition of drug substance is -70°C.
6.	Scientific justification is required for an overfill of 9.2% of solution of infusion as evident from the submitted composition table in the requisite section.	Firm replied that the overfill is needed in order to ensure the labelled amount of active in the solution for infusion. Further, the proposed composition is similar to that of reference product i.e. Cancidas.
7.	Justify for not using the succinic acid as buffering agent in the developed formulation, since the review document of innovator	Firm clarified that the applied formulation is qualitatively similar to the innovator product Cancidas, in which sodium hydroxide or glacial acetic acid are used as pH adjusters and not succinic acid.

	product highlights the importance of succinic acid in the formulation in order to ensure stability during compounding and reconstitution, as well as suitable osmolarity for infusion. It also enables production of a satisfactory cake following lyophilisation	
8.	Submit data of Pharmaceutical equivalence of the applied drug of strength 50mg with the innovator / reference/ comparator product of same strength and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted the comparative study report of applied product against the innovator product Cancidas of Merck Sharp & Dhome.
9.	Caspofungin acetate is highly soluble in aqueous media but sensitive to heat, oxygen and extremes of pH, the submitted manufacturing method did not include any of the precautionary measures to avoid the degradation of active substance due to the above said factors, clarification is required in this regard.	Firm submitted the forced degradation study report of drug product in response of this query.
10.	Justify for keeping the column temperature uptill 45°C by keeping in view the heat sensitivity of applied product.	Firm replied that "Kindly note that the keeping time of the drug product at the column temperature until 45°C is so fast that it is not significant as parameter for the heat sensitivity of the drug product".

Decision:Deferred for submission of legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.

928	**Name, address of Applicant / Importer**	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road Karachi
	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road Karachi **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564,Greece
	Name, address of manufacturer(s)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS 61st km National Road Athens-Lamia, Schimatari Viotias 32009, Greece
	Name of exporting country	Greece

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **original**, legalized CoPP certificate (53851) dated 21-07-2021 issued by National Organization of Medicine for Casglo Powder for concentrate for solution of infusion 50mg/vial. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodicity of routine inspection 3 years. **GMP Certificate:** Firm has submitted GMP Certificate No.:8652/23-02-2021 dated 29-0302021 issued by National Organization for Medicine, Greece. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original, legalized Agency Agreement from Meraki Global PTE Ltd. 20 Collyer Quay #11-05, Singapore. The supply and distribution agreement letter specifies that MERAKI is the supplier of pharmaceutical preparations and Hakimsons involve in the business off distribution, sub distrbutors of pharmaceutical product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 3333 Dated:03-02-2022
	Details of fee submitted	PKR 150,000/ Dated: 28-10-2021
	The proposed proprietary name / brand name	Casglo Powder for concentrate for solution of infusion 70mg/vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 70mg Caspofungin (as acetate) After reconstitution in 10.5ml of water for injection, 1ml of concentrate contains 5.2mg Caspofungin.
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Antimycotic for systemic use, ATC code J02AX04
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x70mg Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved) **CANCIDAS CASPOFUNGIN ACETATE**.
	For generic drugs (me-too status)	Caspogin Powder for concentrate for solution of infusion 50mg/vial of M/s. AJM Pharma Pvt. Ltd. (Reg.no. 106828)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Teva API India Private Limited Manufacturing Site: Gajraula site Plot Nos, A-2, A-2/1, A-2/2, UPSIDC Industrial Area, Bijnor Road, Distt. Amroha Gajraula -244 235 (Uttar Pradesh), India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Forced Degradation Studies
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated and real time stability data are conducted at (-18°C±3°C) and (-70°C±5°C) respectively. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the innovator product German Product Cancidas 50mg Merck Sharp & Dhome Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I clear glass vial closed by bromobutyl stoppers. Closed vials are secured by aluminum seal with a plastic flip-off caps.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of Three batches of 6500 mL batch size production were tested: inverted and upright position. The accelerated stability study data is conducted at 25°C±2°C/60%±5% RH for 6 months. The real time stability study data is conducted at 2-8 °C for 24 months.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid drug sale license of M/s. Hakimson Impex Pvt. Ltd, Karachi.	Firm submitted the valid DSL of applicant which is valid till 19/07/2028.

2.	Submit valid GMP certificate of Manufacturer Abroad ,since the submitted certificate was expired in 2021.	Firm submitted the GMP certificate which was based on inspection conducted on 22-03-2019,issue dated 29-03-2021 and validity was for three years.
3.	Submit legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.	Not submitted.
4.	Submit analytical method verification report of drug substance performed by drug product manufacturer, in accordance with the requirement mentioned in the CTD guidance document approved by Registration Board.	Firm submitted the method transfer for the analytical methods of assay determination, related substances determinations and residual solvents test of Caspofungin Acetate API which are to be transferred from TEVA Laboratories to Anfarm.
5.	Justify the stability conditions adopted for stability studies of drug substance in camparison of stability conditions recommended by innovator product for the drug substance.	Firm replied that they adopted the reference of innovator product approved in USFDA i.e. Cancidas Powder for concentrate for solution of infusion 50mg/vial. According to the review document of innovator brand storage condition of drug substance is -70°C.
6.	Scientific justification is required for an overfill of 9.2% of solution of infusion as evident from the submitted composition table in the requisite section.	Firm replied that the overfill is needed in order to ensure the labelled amount of active in the solution for infusion. Further, the proposed composition is similar to that of reference product i.e. Cancidas.
7.	Justify for not using the succinic acid as buffering agent in the developed formulation, since the review document of innovator product highlights the importance of succinic acid in the formulation in order to ensure stability during compounding and reconstitution, as well as suitable osmolarity for infusion. It also enables production of a satisfactory cake following lyophilisation	Firm clarified that the applied formulation is qualitatively similar to the innovator product Cancidas, in which sodium hydroxide or glacial acetic acid are used as pH adjusters and not succinic acid.
8.	Submit data of Pharmaceutical equivalence of the applied drug of strength 50mg with the innovator / reference/ comparator product of same strength and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product	Firm submitted the comparative study report of applied product against the innovator product Cancidas of Merck Sharp & Dhome.

	shall be submitted and discussed".	
9.	Caspofungin acetate is highly soluble in aqueous media but sensitive to heat, oxygen and extremes of pH, the submitted manufacturing method did not include any of the precautionary measures to avoid the degradation of active substance due to the above said factors, clarification is required in this regard.	Firm submitted the forced degradation study report of drug product in response of this query.
10.	Justify for keeping the column temperature uptill 45°C by keeping in view the heat sensitivity of applied product.	Firm replied that "Kindly note that the keeping time of the drug product at the column temperature until 45°C is so fast that it is not significant as parameter for the heat sensitivity of the drug product".

Decision:Deferred for submission of legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Marketing Authorization holder (MAH) will given the marketing rights of applied product to Meraki Global.

929.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt
	Details of Drug Sale License of importer	**License No:** 05-352-0068-109282D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 18.10.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Hainan Zhonghe Pharmaceutical Co., Ltd.** Haikou Free Trade Zone, No.168 Nanhai Avenue, Haikou City -570216, Hainan Province, P. R. China
	Name, address of manufacturer (s)	**Hainan Zhonghe Pharmaceutical Co., Ltd.** Haikou Free Trade Zone, No.168 Nanhai Avenue, Haikou City-570216, Hainan Province, P. R. China
	Name of exporting country	**China**
	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP (20220050 No. Hainan 20220050) issued by Hainan Provincial Medical Products Administration for HERI (Thymalfasin 1.6 mg) valid until 21-06-2024. The CoPP states that the product is **on free sale in exporting country**. **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (No.HI20190004) issued by Hainan Provincial Medical Products Administration valid until 27-01-2024
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from Hainan Zhonghe Pharmaceutical Co., Ltd. Haikou Free Trade Zone, No.168 Nanhai Avenue, Haikou City -570216, Hainan Province, P. R. China. The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 30th June, 2024.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 30338 dated 26-10-2022
	Details of fee submitted	Rs: 150,000 vide Slip number: 3386239604 Dated : 15/08/2022
	The proposed proprietary name/ brand name	**HERI 1.6 mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**(Thymalfasin 1.6 mg) Thymosin α1**
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Adjuvants, Immunomodulatory drug
	Reference to Finished product specifications	CP 2020/In-house
	Proposed Pack size	2 vial Thymalfasin for Injection and 2 vials diluent/box
	Proposed unit price	Rs.
	Shelf Life	3 years
	Storage Conditions	Store in a refrigerator (2°C to 8°C), sealed in a closed container".
	The status in reference regulatory authorities	**Zadaxin of, <u>AIFA (Italy) approved</u>**
	For generic drugs (me-too status)	**Reg. No:** ..... **Company Name:**. Getz pharma **Brand Name:** Zadaxin **Formulation:** Thymalfasin 1.6 mg **Pack Size:** 2 vial Thymalfasin for Injection and 2 vials diluent/box
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Hainan Zhonghe Pharmaceutical Co., Ltd. **Address:** Unit-4, S2 workshop, Haikou Free Trade Zone, No.168, Nanhai Avenue, Haikou City- 570216, Hainan Province, P.R. China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

<table>
<tr><td></td><td>Stability Studies of Drug Substance
(Conditions & duration of Stability studies)</td><td>Firm has submitted
(a) Summary of stress testing (e.g., heat, humidity, oxidation, photolysis, acid/base): and results:
(b) Summary of accelerated (25°C ± 2°C/RH: 60% ± 5%) and long-term(5°C ± 3°C) testing parameters (e.g., studies conducted):
c) Summary of the stability results observed for the above accelerated and long-term studies:
(d) Proposed storage statement and re-test period (or shelf-life, as appropriate):
The drug substance should be packed in HDPE bottles and stored in a refrigerator (2°C to 8°C), keep away from light; sealed in a closed container with Re-test period 36 months.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has performed Pharmaceutical Equivalence studies of Heri Injection with ZADAXIN. The reference drug product of Thymalfasin for Injection is the innovator drug product marketed in China, that is, Thymalfasin for Injection (trade name: ZADAXIN ®) produced by SciClone Pharmaceuticals Italy S.R.L. Therefore, ZADAXIN was selected as the reference drug product of this product to perform the formulation and process development study.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>The analytical method validation protocols and reports of each test method for the drug product specification parameters are presented below:
<table><tr><th>Protocol title</th><th>Protocol No</th></tr><tr><td>Analytical Method Validation Protocol of Related substances in Thymalfasin for Injection 1.6 mg</td><td>14-TS(RD/P005)-Y001/02-EN</td></tr><tr><td>Analytical Method Validation Protocol of Aggregates in Thymalfasin for Injection 1.6 mg</td><td>14-TS(RD/P005)-P003-EN</td></tr><tr><td>Analytical Method Validation Protocol of Bacterial Endotoxin in Thymalfasin for Injection 1.6 mg</td><td>07-TS(QD/P)-Y154-EN</td></tr><tr><td>Analytical Method Validation Protocol of Sterility in Thymalfasin for Injection 1.6 mg</td><td>07-TS(QD/P)-Y281-EN</td></tr><tr><td>Analytical Method Validation Protocol of Assay by HPLC in Thymalfasin for Injection 1.6 mg</td><td>14-TS(RD/P005)-Y001/01-EN</td></tr></table></td></tr>
</table>

3.2.P.5.3.2 Analytical Method Validation Reports of Thymalfasin for Injection 1.6 mg

The exemplary validation reports of each test method for the drug product specification parameters examined with in-house test method are presented below.

Report title	Report No
Analytical Method Validation Report of Related substances in Thymalfasin for Injection 1.6 mg	14-TS(RD/P005)-R001/02-EN
Analytical Method Validation Report of Aggregates in Thymalfasin for Injection 1.6 mg	14-TS(RD/P005)-R003-EN
Analytical Method Validation Report of Bacterial Endotoxin in Thymalfasin for Injection 1.6 mg	07-TS(QD/R)-Y154-EN
Analytical Method Validation Report of Sterility in Thymalfasin for Injection 1.6 mg	07-TS(QD/R)-Y281-EN
Analytical Method Validation Report of Assay by HPLC in Thymalfasin for Injection 1.6 mg	14-TS(RD/P005)-R001/01-EN

Container closure system of the drug product

Strength	Pack	Description
1.6 mg	2 ml	Neutral borosilicate glass tubular injection vial stoppered with halogenated butyl rubber stopper and aluminium-plastic composite cap.

Sterile Water for Injection is packed in following packs.

Strength	Description
1 ml	Neutral borosilicate glass tubular injection stoppered with Teflon coated halogenated rubber stopper and aluminium-plastic composit

Stability study data of drug product, shelf life and storage conditions

Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at: 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5°C ± 3°C / 60% ± 5 % RH for 36 months as per ICH guidelines.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.	Firm submitted the evidence of availability of applied formulation in Aifa Italy (Zadaxin Injection 1.6mg/ml)

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

CASES OF EXPORT FACILITATION:

Deputy Director PRV/EFD vide its letter dated 22-01-2024 informed that in pursuance of decision of 133rd meeting of the Authority wherein it was decided that for each 100,000 USD worth of export during a fiscal year one molecule will be considered on priority basis. In compliance to this, M/s. Surge Laboratories (Pvt.) Ltd. has achieved the benchmark of more than 100,000 USD during the financial year 2020-2021. Accordingly, the firm has requested for priority consideration of the following molecule

930.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhupura.**

	Name, address of Manufacturing site.	**M/s. Nabiqasim Industries Pvt. Limited 17/24, Korangi Industrial Area, Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate of **M/s. Nabiqasim Industries Pvt. Limited** dated 26-07-2023 based on inspection conducted on 22-05-2023. Firm has submitted copy of GMP certificate of **M/s. Surge Laboratories (Pvt.) Ltd.** dated 09-08-2023 based on inspection conducted on 25-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	Tracking ID X66-V7G-1W4H Application no. 1024 dated 30-01-2024
	The proposed proprietary name / brand name	Challan Number: 764483623 PKR 75,000/- Dated 07-12-2023
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Surgide 50mg Tablet**
	Pharmacotherapeutic Group of (API)	Each tablet contains; Levosulpiride ... 50mg
	Pharmaceutical form of applied drug	Psycholeptics, antipsychotic
	Reference to Finished product specifications	Uncoated Tablet
	Proposed Pack size	Innovator’s specification
	Proposed unit price	10's, 20's, 30's, 60
	The status in reference regulatory authorities	As per SRO
	For generic drugs (me-too status)	AIFA (Italian Medicine Agency and Ministry of Health) Cyprus
	Name and address of API manufacturer.	Scipride tablet 50mg of M/s. Getz Pharma, Karachi (Reg.no. 057903)
	Module-II (Quality Overall Summary)	Alcon Biosciences Pvt. Ltd., India
	Module-III Drug Substance:	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted pharmaceutical equivalence of their product against the comparator product Scipride Tablet 50mg manufactured by Getz Pharma, Karachi. Firm has submitted CDP results of their product against the comparator product Scipride Tablet 50mg in 3 dissolution medias.

STABILITY STUDY DATA

Manufacturer of API	Alcon Biosciences Private Limited. A-1/2104, phase III, GIDC, Vapi–396 195		
API Lot No.	31L01Z2122-001		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	490DS01	490DS01	490DS01
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
No. of Batches	12-05-2022		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nabiqasim Industries (Pvt.) Ltd. has got the approval of the following products to be manufactured: Nixmetic Tablet 500mg Each tablet contains: Mebendazole.....500mg Reg. No.: 107702 Loptas Tablet 130mg Each tablet contains: Potassium Iodide...130mg Reg. No.: 108485 Descol EZ Tablet 10/40 Each film coated tablet contains: Ezetimibe.....10mg

		Atorvastatin Calcium Trihydrate eq. to Atorvastatin 40mg (As per Innovator's Specification) Reg. No.: 108621 Solbovir Tablet 400mg Each film coated tablet contains: Sofosbuvir.....400mg Reg. No.: 108620 Pavifir Tablet 200mg Each film coated tablet contains: Favipiravir.....200mg Reg. No.: 108899 Livent Tablet 0.5mg Each film coated tablet contains: Entecavir Monohydrate eq. to Entecavir.....0.5mg Reg. No.: 108959 Livent Tablet 1mg Each film coated tablet contains: Entecavir Monohydrate eq. to Entecavir.....1mg Reg. No.: 108960
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP/DML Certificate no. S-GMP/22113654 and valid till 03/11/2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Please specify the reference of dissolution medium adopted for dissolution test along with evidence of literature of innovator product, since the release profile of applied product is approximately similar in all three medias.	Firm replied that "The rationale for selecting the dissolution medium/method is as per the recommendation of USP general chapter and ICH guidance document for "Dissolution Testing of Immediate Release Solid Oral Dosage Forms.". Further, Rationale for selecting pH 6.8 media as Qc release media is that Levosulpiride is S-enantiomer of Sulpride. Levosulpiride has a pKa value of 8.5 approximately near to sulpride pKa value 9.12 and partition coefficient of sulpride is 0.42. Sulphide tablet monograph is officially available in JP compendia (enclosed for reference in Annexure-A). 2nd fluid is used as dissolution medium (pH 6.8 Buffer); however we will adapt the proposed dissolution medium (0.1N HCI) as QC release media for our applied product Levosulpiride tablet Range on the basis of PAR of Reference product."
2.	Justify for taking fine powder equivalent to 100mg for making sample solution of 50mg strength tablet	Firm replied that it is typo error and To prepare sample solution for 50 mg strength weigh sample according to average weight of one tablet (i.e. equivalent to 50mg of Levosulpiride) in 100 mL Volumetric flask and dilute the stock preparation by transferring

		5mL of stock solution into 25mL volumetric flask to obtain sample concentration of 0.1mg/ml.
3.	Justify for submitting analytical method validation report of 50mg&100mg strength for 25mg strength tablet, since the sample solution preparation of both strengths are different from each other.	Firm relied that "Since the sample preparation of 25mg strength is different from 50mg strength, we have done separate analytical method validation for Levosulpiride Tablet 25mg'strength, same is enclosed in Annexure-C. Previously, mistakenly validation report of 50mg strength was enclose in dossier of 25mg tablet strength".

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

931.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhupura.**
	Name, address of Manufacturing site.	**M/s. Nabiqasim Industries Pvt. Limited 17/24, Korangi Industrial Area, Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate of **M/s. Nabiqasim Industries Pvt. Limited** dated 26-07-2023 based on inspection conducted on 22-05-2023. Firm has submitted copy of GMP certificate of **M/s. Surge Laboratories (Pvt.) Ltd.** dated 09-08-2023 based on inspection conducted on 25-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 27-04-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	Tracking ID R4R-ZDT-8TY1 Application no. 1023 dated 30-01-2024
	The proposed proprietary name / brand name	Challan Number: 40144728782 PKR 75,000/- Dated 07-12-2023
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Surgide 25mg Tablet**
	Pharmacotherapeutic Group of (API)	Each tablet contains; Levosulpiride ... 25mg
	Pharmaceutical form of applied drug	Psycholeptics, antipsychotic
	Reference to Finished product specifications	Uncoated Tablet

	Proposed Pack size	Innovator's specification
	Proposed unit price	10's, 20's, 30's, 60
	The status in reference regulatory authorities	As per SRO
	For generic drugs (me-too status)	AIFA (Italian Medicine Agency and Ministry of Health) Cyprus
	Name and address of API manufacturer.	Scipride tablet 25mg of M/s. Getz Pharma, Karachi (Reg.no. 057903)
	Module-II (Quality Overall Summary)	Alcon Biosciences Pvt. Ltd., India
	Module-III Drug Substance:	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted pharmaceutical equivalence of their product against the comparator product Scipride Tablet 25mg manufactured by Getz Pharma, Karachi. Firm has submitted CDP results of their product against the comparator product Scipride Tablet 25mg in 3 dissolution medias.

STABILITY STUDY DATA	
Manufacturer of API	Alcon Biosciences Private Limited. A-1/2104, phase III, GIDC, Vapi–396 195
API Lot No.	31L01Z2122-001
Description of Pack (Container closure system)	Alu-PVC Blister

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	681DS01	681DS02	681DS03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
No. of Batches	17-11-2022		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nabiqasim Industries (Pvt.) Ltd. has got the approval of the following products to be manufactured: Nixmetic Tablet 500mg Each tablet contains: Mebendazole.....500mg Reg. No.: 107702 Loptas Tablet 130mg Each tablet contains: Potassium Iodide...130mg Reg. No.: 108485 Descol EZ Tablet 10/40 Each film coated tablet contains: Ezetimibe.....10mg Atorvastatin Calcium Trihydrate eq. to Atorvastatin 40mg (As per Innovator's Specification) Reg. No.: 108621 Solbovir Tablet 400mg Each film coated tablet contains: Sofosbuvir.....400mg Reg. No.: 108620 Pavifir Tablet 200mg Each film coated tablet contains: Favipiravir.....200mg Reg. No.: 108899 Livent Tablet 0.5mg Each film coated tablet contains: Entecavir Monohydrate eq. to Entecavir.....0.5mg Reg. No.: 108959 Livent Tablet 1mg Each film coated tablet contains: Entecavir Monohydrate eq. to Entecavir.....1mg Reg. No.: 108960
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP/DML Certificate no. S-GMP/22113654 and valid till 03/11/2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Please specify the reference of dissolution medium adopted for dissolution test along with evidence of literature of innovator product, since the release profile of applied	Firm replied that "The rationale for selecting the dissolution medium/method is as per the recommendation of USP general chapter and ICH guidance document for "Dissolution

	product is approximately similar in all three medias.	Testing of Immediate Release Solid Oral Dosage Forms.". Further, Rationale for selecting pH 6.8 media as Qc release media is that Levosulpiride is S-enantiomer of Sulpride. Levosulpiride has a pKa value of 8.5 approximately near io sulpride pkA value 9.12 and partition coefficienJ of sulpride is 0.42. Sulpride tablet monograph is bfficially available in JP compendia (enclosed for reference in Annexure-A). 2nd fluid is used as dissolution medium (pH 6.8 Buffer); however we will adapt the proposed dissolution medium (0.1N HCI) as QC release media for our applied product Levosulpiride tablet Range on the basis of PAR of Reference product."
2.	Justify for taking fine powder equivalent to 100mg for making sample solution of 50mg strength tablet	Firm replied that it is typoerror and To prepare sample solution for 50 mg strength weigh sample according to average weight of one tablet (i.e. equivalent to 50mg of Levosulpiride) in 100 mL Volumetric flask and dilute the stock preparation by transferring 5mL of stock solution into 25mL volumetric flask to obtain sample concentration of 0.1mg/ml.
3.	Justify for submitting analytical method validation report of 50mg&100mg strength for 25mg strength tablet, since the sample solution preparation of both strengths are different from each other.	Firm relied that "Since the sample preparation of 25mg strength is different from 50mg strength, we have done separate analytical method validation for Levosulpiride Tablet 25mg'strength, same is enclosed in Annexure-C. Previously, mistakenly validation report of 50mg strength was enclose in dossier of 25mg tablet strength".

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

DEFERRED CASES OF REGISTRATION BOARD:
CASES OF LOCAL MANUFACTURING RECEIVED ON FORM 5-F

932.	Name, address of Applicant / Marketing Authorization Holder	M/s. TriVista Pharmaceuticals
	Name, address of Manufacturing site.	M/s. TriVista Pharmaceuticals 8-KM, Taxila Khanpur Road, District Haripur, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License grant dated 28-04-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section and Capsule (General).

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14388 dated 08-06-2023
	Details of fee submitted	PKR 30,000/- Dated 30-05-2023
	The proposed proprietary name / brand name	Moxivista 400mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: - Moxifloxacin as HCl…..400mg
	Pharmacotherapeutic Group of (API)	Quinolone broad spectrum Antibiotic
	Pharmaceutical form of applied drug	Tablet.
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi Reg.no. 047117
	Name and address of API manufacturer.	M/s. SAAKH Pharma Plot no. C-7/1, North Westren Industrial Zone Port Qasim, Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Comparator product Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi. Batch no. 239F31 Firm has submitted CDP results of their product against Comparator product Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi. Batch no. 239F31 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s. SAAKH Pharma Plot no. C-7/1, North Westren Industrial Zone Port Qasim, Karachi.		
API Lot No.	22GN30-10012		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFT22E007	PFT22E008	PFT22E009
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	26-05-2022	26-05-2022	26-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 83/2020-DRAP (K) dated 23-06-2020 valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings

1.	3.2.S.4.2	Submit Analytical procedure and specification of drug substance by drug product manufacturer, since you have only submitted the analytical procedure by drug substance manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.5	Reference Standards or Materials Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
4.	3.2.S.7	The stability study data of drug substance submitted in section 3.2.S.7.3 is tested on completely different specifications as provided in section 3.2. S.4. Justification is required in this regard how this stability study data represents the same drug substance for which the data in module 3.2.S is submitted. Further, justify for not performing the test of pH, water determination test ,chloride and sulphate test during the stability studies.
5.	3.2.P.2.2.1	Justify, why the pharmaceutical equivalence and comparative dissolution profile was studied against comparator product instead of using innovator product/brand leader.
6.	3.2.P.5.4	Provide batch analysis report of the stability batches in section 3.2.P.5.4.
7.	2.3.R.1.1	Please provide complete calculation of dispensed weight of drug substance per tablet considering the water content and salt factor of active material.

Decision of 330th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit Analytical procedure and specification of drug substance by drug product manufacturer, since you have only submitted the analytical procedure by drug substance manufacturer.	Submitted
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
3.	Reference Standards or Materials Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.	Firm submitted the COA of working standard by M/s. SAAKH Pharma (Pvt.) Ltd. Karachi.
4.	The stability study data of drug substance submitted in section 3.2.S.7.3 is tested on completely different specifications as provided in section 3.2. S.4. Justification is required in this regard how this stability study data represents the same drug substance for which the data in module 3.2.S is submitted. Further, justify for not performing the test of pH, water determination test ,chloride and sulphate test during the stability studies.	Firm replied that we have requested the drug substance manufacturer (SAAKH Pharma) to provide us the DMF after correction till now we did not get DMF, but on telephonic conversation with representative of SAAKH Pharma they told them that the point highlighted is typographic mistake, further, on their request the API Manufacturer performed the test of pH, water determination test, chloride and sulphate test in stability study as per monograph requirement. Firm submitted the stability data of only six month of drug substance
5.	Provide batch analysis report of the stability batches in section 3.2.P.5.4.	Submitted
6.	Please provide complete calculation of dispensed weight of drug substance per tablet	Firm replied that without considering the water content (LOD factor) they dispensed

	considering the water content and salt factor of active material.	the batches, in future they will consider the water content when dispensing the batches.

Decision: Deferred for submission /clarification of following:

- **Submit stability data of drug substance performed at Zone-IVa condition till the claimed re-test date.**
- **Clarify for not considering the water content of drug substance while calculation of dispensed weight of drug substance per tablet.**

933.	Name, address of Applicant / Marketing Authorization Holder	Himark Laboratories (Pvt.) Ltd. Plot no. 37-A, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	Himark Laboratories (Pvt.) Ltd. Plot no. 37-A, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate based upon the evaluation conducted on 28-03-2023.
	Evidence of approval of manufacturing facility	License granted vide letter No. F. 1-67/2005- Lic dated 26TH September,2019. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and Oral Liquid Syrup (general) sections and Cream/Ointment (General) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 25278 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 02-10-2023
	The proposed proprietary name / brand name	Declor Syrup 2.5mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Desloratadine…….0.5mg
	Pharmacotherapeutic Group of (API)	Antihistamine H1 antagonist
	Pharmaceutical form of applied drug	Oral Syrup
	Reference to Finished product specifications	In-house
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Desora 0.5mg/ml Syrup of M/s. Continental Pharma (Reg.no.055192)
	Name and address of API manufacturer.	M/s. Morepen Laboratories Limited Village Masulkhana, Perwanoo Distt. Solan Perwanoo Himachal Pardesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence their product against the clarinex Syrup of M/s. Merck & Co. Inc.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Morepen Laboratories Limited Village Masulkhana, Perwanoo Distt. Solan Perwanoo Himachal Pardesh, India.		
API Lot No.	DH-0106		
Description of Pack (Container closure system)	Amber color pet bottle with Aluminium Cap is packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12,18,24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HFW-H (Drugs) 56/98 issued dated 10/01/2022 by Health & Family Welfare Department Himachal Pardesh and valid for two years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted commercial invoice without DRAP attestation.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Drug substance analytical procedure shall be submitted from both drug substance manufacturer and drug product manufacturer.
2.	3.2. P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
3.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
4.	3.2.P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
5.	3.2.P.5.2	Clarification required regarding the instrument used for assay of drug product either the assay has performed on HPLC or UV spectrophotometer. Since the assay method given in section 3.2.P.5.2 is on UV while validation report and stability data revealed that the assay has been performed on HPLC. Provide detailed procedure of uniformity of dosage unit test and deliverable volume test.
6.	3.2.P.5.4	Provide results of impurity testing relevant to the presence of ethylene glycol and diethylene glycol contamination in the drug in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
7.	3.2.P.8	Justify the batch size against the number of units to complete stability studies. Documents confirming import of drug substance with approval from DRAP I&E Office, shall be submitted. Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Drug substance analytical procedure shall be submitted from both drug substance manufacturer and drug product manufacturer.	Firm submitted the analytical procedure of drug substance from drug product manufacturer and drug substance manufacturer. However, the assay procedure used for analysis of drug substance by drug product manufacturer is different from the assay method recommended by drug substance manufacturer.

2.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Not submitted
3.	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	Submitted
4.	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm replied that they have submitted samples of Glycerine and sorbitol 70% for impurity testing Diethylene Glycol(DEG) and Ethylene Glycol (EG) to CDL Karachi. Evidence of receipt of submission is submitted by the firm.
5.	Clarification required regarding the instrument used for assay of drug product either the assay has performed on HPLC or UV spectrophotometer. Since the assay method given in section 3.2.P.5.2 is on UV while validation report and stability data revealed that the assay has been performed on HPLC.	Reply not submitted by the Firm.
6.	Provide detailed procedure of uniformity of dosage unit test and deliverable volume test.	Reply not submitted by the Firm.
7.	Provide results of impurity testing relevant to the presence of ethylene glycol and diethylene glycol contamination in the drug in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm replied that they have submitted samples of Glycerine and sorbitol 70% for impurity testing Diethylene Glycol(DEG) and Ethylene Glycol (EG) to CDL Karachi. Evidence of receipt of submission is submitted by the firm.
8.	Justify the batch size against the number of units to complete stability studies.	Firm replied that batch size is enough for stability study as 10 bottles are required for each level of accelerated and long term stability which are 80 bottles required.
9.	Documents confirming import of drug substance with approval from DRAP I&E Office, shall be submitted.	Firm replied that raw materials are directly delivered to factory. Air way bills are attached. However the airway bills are not attached in the reply.
10	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm replied that HPLC record is maintained manually.
11	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted.

Decision: Deffered for submission of following:

- **Justify for adopting the different assay method of drug substance by drug product manufacturer from the assay method recommended by drug substance manufacturer.**
- **Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.**
- **Clarification required regarding the instrument used for assay of drug product either the assay has performed on HPLC or UV spectrophotometer. Since the assay method given in section 3.2.P.5.2 is on UV while validation report and stability data revealed that the assay has been performed on HPLC.**
- **Provide detailed procedure of uniformity of dosage unit test and deliverable volume test.**
- **Documents confirming import of drug substance with approval from DRAP I&E Office, shall be submitted.**

934.	Name, address of Applicant / Marketing Authorization Holder	M/s. Palpex Pharmaceuticals (Pvt.) Ltd.-FD-46-A8, ST-1, Sector 38,Korangi Creek Industrial Park Karachi.
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.33018: 17-11-2022
	Details of fee submitted	PKR 75,000/-: 03-10-2022
	The proposed proprietary name / brand name	Tobton 3mg Ophthalmic solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Solution Contains: Tobramycin…3mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tobrex ophthalmic solution (USFDA Approved)
	For generic drugs (me-too status)	Tobnove Sterile Ophthalmic Solution by Novex Pharma
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substancess (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40oC ± 2oC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30oC ± 2oC / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Eyebrex 3mg/ml eye drops of Barrett Hodgson
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.		
API Lot No.	TB2007011		
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	215E	234E	235E
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2020	01-2021	01-2021
Date of Initiation	10-09-2020	10-01-2021	10-01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2
2.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
3.	The assay limit specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.
4.	Submit API stability study data till the shelf life since real time stability data is submitted till 9 months only.
5.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.
6.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.
7.	Provide preservative effectiveness studies.
8.	Justify why the product specifications do not include a test for the assay of preservative contents.
9.	Justify why the assay calculation formula is different from that specified in USP monograph.
10.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.
11.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.
12.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated along with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.
14.	Submit evidence of procurement of drug substance including ADC attested invoice / clearance certificate.

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

Sr. No	**Shortcomings communicated**	**Response by the firm**

1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted analytical procedure of drug substance by drug product manufacturer is not in accordance with USP monograph of Tobramycin.
2.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Not submitted
3.	The assay limit specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Not submitted
4.	Submit API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted stability data of drug substance is not as per zone IV-A conditions.
5.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Firm replied that they have made 3 lab scale batches of applied product, results of finished product and stability studies are satisfactory.
6.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non-availability of innovator product firm has performed pharmaceutical equivalence against a comparator product.
7.	Provide preservative effectiveness studies.	Submitted
8.	Justify why the assay calculation formula is different from that specified in USP monograph.	Revised assay procedure has been submitted by the firm.
9.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Assay procedure on which verification studies has performed, is different from that specified in USP monograph.
10.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
11.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	Firm replied that new stability chamber for semi permeable container is to be purchase. Further, firm has also not performed the water loss study while performing the stability studies of drug product.
12.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated along with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	submitted
13.	Submit evidence of procurement of drug substance including ADC attested invoice / clearance certificate.	Submitted

Decision: Deferred for submission of following:

- **Justify for not adopting the same assay procedure of drug substance as recommended in the USP monograph of "Tobramycin".**
- **Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2. S.4.3.**
- **The assay limit specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.**
- **Submit stability data of drug substance is as per zone IV-A conditions till the claimed re-test date.**
- **Justify for performing the verification studies on assay procedure different from assay method recommnended by USP.**
- **Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.**

935.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-05-2021 specifying Dry powder Sachet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 612 dated 04-07-2022
	Details of fee submitted	PKR 150,000/- Dated 15-05-2022
	The proposed proprietary name / brand name	Racet Sachet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Racecadotril, MDM….10mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Pharmaceutical form of applied drug	White to off-white granules for oral suspension
	Reference to Finished product specifications	In-House Specification
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec Infants 10mg, granules Medicines and Healthcare Regulatory Agency (MHRA)
	For generic drugs (me-too status)	Not Applicable.

	Name and address of API manufacturer.	Athena Drug Delivery Solutions Pvt. Ltd. Address: Manufacturing Site, Plot No: A-1 to A-5, MIDC, Chemical Zone, Near ion Exchange, Ambernath (W) District-Thane-421501, MAHARASHTRA, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: Real Time: RD/GMP/17022, RD/GMP/17023, RD/GMP/17024 Accelerated Time: RD/GMP/17022, RD/GMP/17023, RD/GMP/17024
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Reference product that is Hidrasec Sachet 10mg from Abbot Laboratories (Pakistan) Ltd by performing quality tests i.e. Dissolution, Assay. CDP has been performed against the same brand that is Hidrasec Sachet 10mg from Abbot Laboratories (Pakistan) Ltd in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Linearity, Range, Accuracy, Precision, Specificity, Repeatability, Robustness,

STABILITY STUDY DATA	
Manufacturer of API	Athena Drug Delivery Solutions Pvt. Ltd. Address: Manufacturing Site, Plot No: A-1 to A-5, MIDC, Chemical Zone, Near ion Exchange, Ambernath (W) District-Thane-421501, MAHARASHTRA, INDIA
API Lot No.	21221
Description of Pack (Container closure system)	Filled in Sachet
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RC-01	RC-02	RC-03
Batch Size	2000 Sachets	2000 Sachets	2000 Sachets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Athena Drug Delivery Solutions Pvt. Ltd. Certificate No: NEW-WHO-GMP/CERT/KD/98377/2021/11/34933 Valid till: 02-Feb-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice No: INV-21-1521 Dated: 02-08-2021 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
	Provide specification and detailed analytical procedures used for the testing of drug substance by drug product manufacturer.	Submitted
	Provide analytical Method verification studies of drug substance performed by the drug product manufacturer.	Submitted
	Justify for keeping the high RPM speed while performing the CDP comparing the dissolution procedure specified in section 3.2.P.5.2 with the RPM speed of 50. Further, justify the quantity of surfactant used in each media while performing the comparative dissolution profiling of drug product, referring to the concentration of Sodium dodecyl sulphate mentioned in the dissolution procedure of drug product in section 3.2. P.5.2.	Firm replied that "The drug showed poor dissolution in all the mediums as drug has poor solubility (BCS class II drug), therefore, in order to improve dissolution rate high RPM speed is considered while performing CDP. However, fresh CDP report with satisfactory results is also being submitted which is conducted with 50 RPM speed. Further, sodium dodecyl sulphate used as surfactant with low concentration to enhance discriminatory power of the test i.e., 1 %".
	Results of comparative dissolution profile mentioned the salt form of active ingredient i.e. racecadotril as besylate, clarify the salt form of API used in the manufacturing of drug product.	Firm replied that "The salt form of API used in the manufacturing of drug product is Racecadotril. API COA also attached for reference. Further, corrected report for CDP also attached with API Racecadotril".
	Scientific justification is required for using different method of dissolution	Firm replied that Slight modification has been done in testing procedure of Dissolution

<table>
<tr><td></td><td>testing from that specified by the drug substance manufacturer i.e. M/s. Athena in section 3.2.S.4.2. Similarly, assay procedure used by drug product manufacturer is different from assay procedure specified by the bulk manufacturer, justification is required in this regard.</td><td>and Assay in comparison with procedure specified by drug substance manufacturer i.e., M/s Athena including decrease in quantity of salt Potassium dihydrogen phosphate and mobile phase ratio. However, modified method has been validated and found in compliance with all the requirements.
Following variation has been observed in analytical method of drug substance and drug product despite the applicant imported ready to fill granules of racecadotril.
<table>
<tr><th>Analytical method of drug substance adopted by drug substance Manufacturer</th><th>Analytical method of drug product adopted by drug product Manufacturer</th></tr>
<tr><td>Assay:
Mobile phase ratio:
45 volumes of phosphate buffer solution pH 2.5 and 55 volumes of Acetonitrile.
Diluent:
25 volumes of phosphate buffer solution pH 2.5 and 75 volumes of Methanol.</td><td>Assay:
Mobile phase ratio:
40 volumes of phosphate buffer solution pH 2.5 and 60 volumes of Acetonitrile.
Diluent:
Same as of mobile phase.</td></tr>
<tr><td>Dissolution:
Chromatographic condition:
Injection volume:10µl
Column oven tep:30°C</td><td>Dissolution:
Chromatographic condition:
Injection volume:50µl
Column oven tep:35°C</td></tr>
</table></td></tr>
<tr><td></td><td>Justify for not including the test of loss on drying and microbial limit test in the specification of finished product since these tests are the part of specification of racecadotril granules manufactured by M/s. Athena DDS Pvt. Ltd.</td><td>Revised specification has submitted by the Firm in which both tests are included.</td></tr>
<tr><td></td><td>Justify for not including the test of loss on drying and microbial limit test while performing the stability studies of finished product since these tests are the part of stability data of racecadotril granules manufactured by M/s. Athena DDS Pvt. Ltd</td><td>Firm replied that “Both test including Loss on drying and Microbial limit test are performed while testing and release of drug substance. Additionally, loss on drying test also performed during in-process testing. Further, as per our internal Stability Studies SOP, microbial limit test will be performed at the end of shelf-life studies i.e., 24 months. However, both tests have been included in revised finished product specification and performed on long-term stability samples for which results found satisfactory. Batch-wise</td></tr>
</table>

		Stability summary report with incorporation of both tests results attached as well.

Decision of 331st meeting of Registration Board:
Deferred for justification of using different method of assay and dissolution testing from that specified by the drug substance manufacturer, since firm has imported ready to fill granules with the defined specifications and analytical procedure by drug substance manufacturer.

Response of the Firm:
Firm replied that they adopted the assay method in accordance with the assay procedure of drug substance manufacturer and accordingly submitted the amended analytical procedure of drug product.

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

936.	Name, address of Applicant / Marketing Authorization Holder	**Variant Pharmaceuticals (Pvt.) Ltd**
	Name, address of Manufacturing site.	**Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqpur Road District Sheikhupura.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10572 dated 27/04/2022
	Details of fee submitted	PKR 30,000/-: dated 09/03/2022
	The proposed proprietary name / brand name	V-MONT 05mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable tablet contains Montelukast Sodium eq. to Montelukast …..5mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Leukotriene antagonist
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 5mg tablet by MERCK & CO., INC, USFDA Approved.
	For generic drugs (me-too status)	BRONSECUR 5 mg tab by M/s Pfizer Pharma (Pvt.) Ltd., Reg. No. 061335
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized)
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd.

		Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China. P.C.:317016
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Montelukast Sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(201310301, 201310302,201310303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Floaid 5mg Tablet by M/s. Highnoon Labs Ltd, Reg.no. 032075 Batchno.212149, expiry date 07-2023. by performing quality tests (Identification, Assay, Dissolution,). CDP has been performed against the same brand that is Floaid 5mg Tablet by M/s. Highnoon Labs Ltd, Reg.no. 032075 Batchno.212149, expiry date 07-2023, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China. P.C.:317016	

API Lot No.	11001-200509		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	11-08-2021	24-08-2021	25-08-2021
Date of Initiation	23-08-2021	28-08-2021	28-08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20180033 issued by China FDA valid till 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 02/03/2020 is submitted wherein the permission to import different APIs including Montelukast Sodium for the purpose of test/analysis and stability studies is granted. Invoice # TYI2020704211 AD date 04-07-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	3.2.S.4.2: Analytical procedures Provide detailed analytical procedures for the testing of drug substance by drug product manufacturer. 3.2.S.4.3: Validation of analytical procedures Provide analytical Method validation studies performed by the Drug Product manufacturer.	Firm submitted the analytical procedure and analytical verification report of drug substance by drug product manufacturer.
2.	Justify the use of a different analytical method for assay testing of drug product in	Firm submitted the analysis sheet in which the sample preparation method is in accordance

	terms of concentration of sample solution and standard solution from that specified in USP monograph.	with USP monograph of montelukast chewable tablet

Decision of 322nd meeting of Registration Board:
Deferred for justification of using Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine as specified by USP monograph.

Response of the Firm:
Firm replied initially dated 21-08-2023 that they have arranged Montelukast Dicyclohexamine working standard and the COA of working standard is submitted as an evidence. Late, submitted the performance report of assay and dissolution testing performed at 24month time point of stability study of all three trial batches using the working standard Montelukast Dicyclohexamine.

Decision of 331st meeting of Registration Board:
Deferred for justification of using working standard of Montelukast Dicyclohexamine purchased from M/s. Dhanuka Laboratories Ltd., India instead of using primary/secondary reference standard supplied from API manufacturer of applied formulation i.e. M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd.

Response of the Firm:
Firm replied that they import Montelukast Sodium for R&D purpose from M/s. Zhejiang Tianyu Pharmaceuticals Co. Ltd and they provided them Montelukast sodium working standard with that shipment, later when they submitted the dossier then the case was deferred in 322nd meeting of Registration Board for not using Montelukast Dicyclohexylamine as working standard. They demand Dicyclohexylamine working standard from M/s. Zhejiang Tianyu Pharmaceuticals Co. Ld. But it was not available and due to COVID situation the import from China was very difficult then we arrange the working standard from M/s. Dhanuka Laboratories India because they want to clarify the shortcomings on immediate basis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

937.	Name, address of Applicant / Marketing Authorization Holder	**Variant Pharmaceuticals (Pvt.) Ltd**
	Name, address of Manufacturing site.	**Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqpur Road District Sheikhupura.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11698 dated 14/05/2022
	Details of fee submitted	PKR 30,000/-: dated 29/04/2022
	The proposed proprietary name / brand name	V-MONT 04mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains Montelukast Sodium eq. to Montelukast …..4mg
	Pharmaceutical form of applied drug	Sachet.
	Pharmacotherapeutic Group of (API)	Leukotriene antagonist
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Montelukast 4 mg Granules by TORRENT PHARMA (UK) Ltd, MHRA approved.
	For generic drugs (me-too status)	FLOAID 4mg Sachet by M/s Highnoon Labs Ltd, Reg. No. 044768
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized)
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China. P.C.:317016
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Montelukast Sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(201310301, 201310302,201310303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is FLOAID 4mg Sachet by M/s Highnoon Labs Ltd, Reg. No. 044768 by performing quality tests (Identification, Assay, Dissolution,). CDP has been performed against the same brand that is FLOAID 4mg Sachet by M/s Highnoon Labs Ltd, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China. P.C.:317016			
API Lot No.	11001-200509			
Description of Pack (Container closure system)	Alu-Alu Sachet packed in unit carton			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	T-001	T-002	T-003	
Batch Size	1000 Sachet	1000 Sachet	1000 Sachet	
Manufacturing Date	03-09-2021	07-09-2021	07-09-2021	
Date of Initiation	08-09-2021	11-09-2021	11-09-2021	
No. of Batches	03			
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20180033 issued by China FDA valid till 14-03-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 02/03/2020 is submitted wherein the permission to import different APIs including Montelukast Sodium for the purpose of test/analysis and stability studies is granted. Invoice # TYI2020704211 AD date 04-07-2020		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm

	3.2.S.4.2: Analytical procedures Provide detailed analytical procedures for the testing of drug substance by drug product manufacturer. 3.2.S.4.3: Validation of analytical procedures Provide analytical Method validation studies performed by the Drug Product manufacturer.	Firm submitted the analytical procedure and verification report of drug substance by drug product manufacturer.

Decision of 322nd meeting of Registration Board:
Deferred for justification of using Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine as specified by USP monograph.

Response of the Firm:
Firm replied initially dated 21-08-2023 that they have arranged Montelukast Dicyclohexamine working standard of M/s. Dhanuka Laboratories Ltd., India and the COA of working standard is submitted as an evidence. Late, submitted the performance report of assay and dissolution testing performed at 24month time point of stability study of all three trial batches using the working standard Montelukast Dicyclohexamine.

Decision of 331st meeting of Registration Board:
Deferred for justification of using working standard of Montelukast Dicyclohexamine purchased from M/s. Dhanuka Laboratories Ltd., India instead of using primary/secondary reference standard supplied from API manufacturer of applied formulation i.e. M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd.

Response of the Firm:
Firm replied that they import Montelukast Sodium for R&D purpose from M/s. Zhejiang Tianyu Pharmaceuticals Co. Ltd and they provided them Montelukast sodium working standard with that shipment, later when they submitted the dossier then the case was deferred in 322nd meeting of Registration Board fir not using Montelukast Dicyclohexylamine as working standard. They demand Dicyclohexylamine working standard from M/s. Zhejiang Tianyu Pharmaceuticals Co. Ld. But it was not available and due to COVID situation the import from China was very difficult then we arrange the working standard from M/s. Dhanuka Laboratories India because they want to clarify the shortcomings on immediate basis.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar
The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of additional section of "Dry Powder Inhaler Capsule section (General)" to M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar.

938.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32464 dated 11/11/2022

	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 100/50mcg RotaCapsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……100mcg Salmeterol Xinafoate ……50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 100mcg + 50Mcg GSK Pakistan. (Reg.no.074726)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at

		acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has not submitted by the firm.		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India		
API Lot No.		Firm has not mentioned the API lot no. of both drug substances.		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.		T-46	T-47	T-48
Batch Size		500 Capsule	500 Capsule	500 Capsule
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		25-12-2021	25-12-2021	25-12-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted		

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.
5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.

10	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.
11	3.2.P.5.4	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
12	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.
13	3.2.P.8	Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. Provide Reference of previous approval of applications with stability study data of the firm (if any) Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
14	2.3 R.1.1	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR,please provide the calculations.

Decision of 323rd meeting of Registration Board:
Deferred for submission of reply of above-cited shortcomings within six month.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.	Firm submitted the revised specification of drug product but microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
2.	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is	Firm only submitted the specification and analytical procedure of drug substance by drug substance manufacturer but did not submitted the specification and analytical procedure of drug substance adopted by drug product manufacturer.

	required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	
3.	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Firm did not submit the response of this query.
4.	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph.	Firm only submitted the revised COAs of drug substance in which results of Optical rotation test included.
5.	Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.	Firm did not submit the response of this query.
6.	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.	Submitted
7.	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.	Firm replied that their inhaler device is consist of three components included mouthpiece, rotacap chamber and base.
8.	Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins).	Firm submitted the revised composition of drug product in accordance with innovator product.

<table>
<tr><td>9.</td><td colspan="2">Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
Firm submitted the following table data in their reply:
<table>
<tr><th>API</th><th>Innovator Spec.</th><th>Winbrains spec.</th></tr>
<tr><td>Fluticasone propionate</td><td>92 micrograms/inhalation delivered</td><td>90 micrograms/inhalation delivered</td></tr>
<tr><td>Salmeterol Xinafoate</td><td>47 micrograms/inhalation delivered</td><td>46 micrograms/inhalation delivered</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation.
Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.</td><td>Firm submitted the pharmaceutical equivalence report against the Seretide Diskus 50/100mcg Powder for inhalation (The inhalation powder is contained in blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device. The plastic devices are available in cardboard containers, which hold) (Batch no.170930 Mfg date: 05-2021 and Expiry date: 04-2024), while firm in its report described the reference product as white capsule orange body hard gelatin capsule shell no.3 filled with white to off white color powder.
Further, microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted report.</td></tr>
<tr><td>11.</td><td>Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.</td><td>Not submitted the response of this query.</td></tr>
<tr><td>12.</td><td>Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph.</td><td>Firm</td></tr>
<tr><td>13.</td><td>Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.</td><td>Firm submitted the revised specification including the performance tests.</td></tr>
<tr><td>14.</td><td>Provide analytical method verification report of drug product in compliance of USP monograph.</td><td>Not submitted the reply of this query</td></tr>
<tr><td>15.</td><td>Justify for not performing the test of microbial</td><td>Not submitted the reply of this query</td></tr>
</table>

	enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	
16.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Not submitted the reply of this query
17.	Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Not submitted the reply of this query
18.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of commercial invoice without attestation from DRAP.
19.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Not submitted the reply of this query
20.	Provide Reference of previous approval of applications with stability	Not submitted the reply of this query

	study data of the firm (if any)	
21.	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
22.	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.	Not submitted the reply of this query

Decision of 333rd meeting of Registration Board:

Deferred for submission of reply to following shortcomings:

- Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
- Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
- Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
- Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.
- Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.
- Provided details regarding the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration) are different from that of innovator drug product.
- Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.
- Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
- Provide analytical method verification report of drug product in compliance of USP monograph.
- Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.
- Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
- Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.

- Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
- Provide certificate of analysis of reference standard /working standard used for testing of the product.
- Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product.
- Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.
- Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.

Response of the Firm:

Sr.no.	Decision of 333rd meeting of RB	Response of the Firm
1.	Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.	Firm submitted the revised specification of finished product.
2.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	Firm submitted the specification of both drug substance different from the specification of drug substance recommended by drug substance manufacturer.
3.	Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.	Firm submitted an incomplete verification report of drug substance by drug product manufacturer.
4.	Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.	Reply not submitted by the firm.
5.	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.	Reply not submitted by the firm.
6.	Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.	Firm submitted pharmaceutical equivalence report which again not contain the results of foreign particulate matter and Delivered Dose Uniformity test.

7.	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.	Reply not submitted by the firm.
8.	Provide analytical method verification report of drug product in compliance of USP monograph.	Firm submitted an incomplete verification report of drug product by drug product manufacturer.
9.	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.	Firm submitted the revised batch analysis report in which the numerical results of test of microbial enumeration test and test for specified microorganism and foreign particulate matter test is not given instead the statement of nil and complies is mentioned.
10.	Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	Reply not submitted by the firm.
11.	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.	Firm submitted only the revised stability data sheets without any performance report/raw data sheets of these tests.
12.	Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Submitted
13.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted
14.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted Form-6 attested by DRAP office without mentioning the lot number of drug substance has been used in manufacturing of each batch of drug product.
15.	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.	Submitted the same BMR which is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.
16.	Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.	Reply not submitted by the firm.

Decision: Deferred for submission of following:

- **Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.**
- **Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.**
- **Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.**

- **Submit pharmaceutical equivalence report including the result of all the test mentioned in the specification of drug product.**
- **Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.**
- **Provide analytical method verification report of drug product in compliance of USP monograph.**
- **Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**
- **Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.**
- **Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.**

939.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32465 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 250/50mcg Rota Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……250mcg Salmeterol Xinafoate ……50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 250mcg + 50mcg GSK Pakistan. (Reg.no.074727)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities,

		physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has submitted against the brand leader seretide Rotacaps 250/50mcg of M/s. Glaxo Smith Kline B.no. R102 Exp date 11-2023 (Identification,assay)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India
API Lot No.	Firm has not mentioned the API lot no. of both drug substances.
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-49	T-50	T-51
Batch Size	500 Capsule	500 Capsule	500 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	25-12-2021	25-12-2021	25-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer,since it was evident from the batch analysis report that you have performed Particle size test by Malvern.

5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.
10.	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.
11.	3.2.P.5.4	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
12.	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.
13.	3.2.P.8	Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. Provide Reference of previous approval of applications with stability study data of the firm (if any) Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

14.	2.3 R.1.1	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR,please provide the calculations.
15.	Amendment in QOS (Module 2) for above points.	

Decision of 323rd meeting of Registration board:
Deferred for submission of reply of above-cited shortcomings within six month.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.	Firm submitted the revised specification of drug product but microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
2.	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	Firm only submitted the specification and analytical procedure of drug substance by drug substance manufacturer but did not submitted the specification and analytical procedure of drug substance adopted by drug product manufacturer.
3.	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Firm did not submit the response of this query.
4.	Drug substance specifications shall include test of specific optical rotation as	Firm only submitted the revised COAs of drug substance in which results of Optical rotation test included.

<table>
<tr><td></td><td>recommended by BP monograph.</td><td></td></tr>
<tr><td>5.</td><td>Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.</td><td>Firm did not submit the response of this query.</td></tr>
<tr><td>6.</td><td>Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.</td><td>Submitted</td></tr>
<tr><td>7.</td><td>Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.</td><td>Firm replied that their inhaler device is consist of three components included mouthpiece, rotacap chamber and base.</td></tr>
<tr><td>8.</td><td>Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins).</td><td>Firm submitted the revised composition of drug product in accordance with innovator product.</td></tr>
<tr><td>9.</td><td colspan="2">Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
Firm submitted the following table data in their reply:
<table>
<tr><td>API</td><td>Innovator Spec.</td><td>Winbrains spec.</td></tr>
<tr><td>Fluticasone propionate</td><td>92 micrograms/inhalation delivered</td><td>90 micrograms/inhalation delivered</td></tr>
<tr><td>Salmeterol Xinafoate</td><td>47 micrograms/inhalation delivered</td><td>46 micrograms/inhalation delivered</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation.
Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.</td><td>Firm submitted the pharmaceutical equivalence report against the Seretide Diskus 50/100mcg Powder for inhalation (The inhalation powder is contained in blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device. The plastic devices are available in cardboard containers, which hold) (Batch no.170930 Mfg date: 05-2021 and Expiry date: 04-2024), while firm in its report described the reference product as white capsule orange body hard gelatin capsule shell no.3 filled with white to off white color powder.
Further, microbial enumeration test ,test for specified microorganism, foreign particulate matter</td></tr>
</table>

		and Delivered Dose Uniformity test was not included in the submitted report.
11.	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.	Not submitted the response of this query.
12.	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph.	Firm submit the analytical procedure of drug product.
13.	Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.	Firm submitted the revised specification including the performance tests.
14.	Provide analytical method verification report of drug product in compliance of USP monograph.	Not submitted the reply of this query
15.	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	Not submitted the reply of this query
16.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Not submitted the reply of this query
17.	Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing	Not submitted the reply of this query

	for each analysis performed during the study.	
18.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of commercial invoice without attestation from DRAP.
19.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Not submitted the reply of this query
20.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted the reply of this query
21.	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
22.	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.	Not submitted the reply of this query

Decision of 333rd meeting of Registration Board:

Deferred for submission of reply to following shortcomings:

- Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
- Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
- Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
- Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.
- Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.
- Provided details regarding the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration) are different from that of innovator drug product.

- Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.
- Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
- Provide analytical method verification report of drug product in compliance of USP monograph.
- Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.
- Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
- Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.
- Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
- Provide certificate of analysis of reference standard /working standard used for testing of the product.
- Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product.
- Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.
- Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.

Response of the Firm:

Sr.no.	Decision of 333rd meeting of RB	Response of the Firm
1.	Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.	Firm submitted the revised specification of finished product.
2.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	Firm submitted the specification of both drug substance different from the specification of drug substance recommended by drug substance manufacturer.
3.	Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability	Firm submitted an incomplete verification report of drug substance by drug product manufacturer.

	(method precision) performed by the Drug Product manufacturer.	
4.	Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.	Reply not submitted by the firm.
5.	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.	Reply not submitted by the firm.
6.	Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.	Firm submitted pharmaceutical equivalence report which again not contain the results of foreign particulate matter and Delivered Dose Uniformity test.
7.	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.	Reply not submitted by the firm.
8.	Provide analytical method verification report of drug product in compliance of USP monograph.	Firm submitted an incomplete verification report of drug product by drug product manufacturer.
9.	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.	Firm submitted the revised batch analysis report in which the numerical results of test of microbial enumeration test and test for specified microorganism and foreign particulate matter test is not given instead the statement of nil and complies is mentioned.
10.	Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	Reply not submitted by the firm.
11.	Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.	Firm submitted only the revised stability data sheets without any performance report/raw data sheets of these tests.
12.	Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Submitted
13.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted
14.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in	Firm submitted Form-6 attested by DRAP office without mentioning the lot number of drug substance has been used in manufacturing of each batch of drug product.

	manufacturing of these batches of drug product.	
15.	Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.	Submitted the same BMR which is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.
16.	Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.	Reply not submitted by the firm.

Decision: Deferred for submission of following:

- **Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.**
- **Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.**
- **Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.**
- **Submit pharmaceutical equivalence report including the result of all the test mentioned in the specification of drug product.**
- **Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.**
- **Provide analytical method verification report of drug product in compliance of USP monograph.**
- **Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**
- **Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.**
- **Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.**

940.	Name, address of Applicant / Marketing Authorization Holder	**M/s Citi Pharma Private Limited**
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10867 dated 29/04/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Cefask Capsule 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as Trihydrate 200mg
	Pharmaceutical form of applied drug	Oral Capsule
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin antibiotic

	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	2x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200 mg CAPSULE by SANOFI Aventis Spain Approved
	For generic drugs (me-too status)	Cefiget 200 mg Capsule by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefixime drug substance is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36th month Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CFM1602001, CFM1602002, CFM1602003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand Product: Maxophine 200mg Capsule Manufacturer: Global Pharmaceutical (Pvt.) Ltd. Batch no: 20H097 Mfg Date: 08-2020
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur		
API Lot No.	Not mentioned		
Description of Pack (Container closure system)	Hard gelatin shell capsule, blistered in alu-pvc packed in standard unit carton in 2x5s provided with leafinsert inside.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRA-001	TRA-002	TRA-003
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	1.5.7	In section 1.5.7, you have claimed USP specification for drug product while in section 3.2.P.5.2 JP monograph for cefixime capsule has been attached which revealed that product is comply with JP specification. Clarify, how 200mg potency capsule comply dissolution acceptance criteria of JP monograph, since it is applicable for 50mg and 100mg.	Firm replied that We have to revised the specification of drug product as approved by DRAP, but firm has not submitted the fee for change of specification.

		Revised the specification of drug product along with requisite fee as per the monograph of cefixime capsule approved by DRAP dated 22nd March,2022 copy of monograph available on DRAP official website.	
2.	3.2.S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."	Firm submitted the reply in which it is stated that "As mentioned in section 4.2 the analytical methods applied in course of release testing of Cefixime are based on the monograph of Cefixime of USP 42. These methods are followed without any deviation".
3.	3.2. S.4.4	Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of different batches than that used in the manufacturing of stability batches.	Firm submitted the COA of three batches of API.
4.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.	Firm has submitted the requisite information.
5.	3.2.S.7	The manufacturing date of API batches was feb,2016 while the approval of cefixime API was granted on 24th July, 2018 by DRAP as evident from the submitted approval letter. Clarify the manufacturing of cefixime API prior grant of approval from DRAP.	In the reply Firm submitted the stability data of different batches of drug substance which were manufactured in October,2018 and having batch no. (CFM1602001, CFM1602002, CFM1602003)
6.	3.2.P.2.2.1	Conclusion of comparative dissolution profile of cefixime capsule specified the f2 values of paracetamol and caffeine, clarification is required in this regard.	Firm in their reply stated that "it was typographic error and rectified," but not submitted the correct CDP report.
7.	3.2.P.5.1	Scientific justification is required for using different assay method from that specified in JP monograph with reference to the	Firm replied that they have now switches over to the monograph of cefixime capsule approved by DRAP. However, the specifications of drug

		chromatographic condition and preparation of standard and sample solutions. According to JP monograph the assay limit should be not less than 90.0% and not more than 105.0% of the labelled potency of cefixime, justify, for keeping the wider acceptance criteria for assay of drug product than JP specifications i.e. 90% to 110%.	product given in the reply was not comply with the said monograph of cefixime capsule
8.	3.2.P.5.2	Firm again submitted the copy of monograph of JP instead of submitting the analytical procedure in accordance with DRAP approved monograph of cefixime capsule.	
9.	3.2.P.5.3	Analytical method validation report submitted in the reply was also not complying the claim pharmacopeial reference of drug product i.e. DRAP's approved monograph of cefixime capsule.	
10.	3.2.P.5.4	Firm submitted the batch analysis report which evident that the specifications of quality test were not in accordance claimed pharmacopeial. Further the results of dissolution test were also included in batch analysis report.	
11.	3.2.P.8	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has not submitted the requisite information.
12.	3.2P.8	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Firm submitted the supportive documents of different stability batches of drug product. Stability summary data sheets were of batch no. (TRA-001,TRA-002,TRA-003),while supportive documents (chromatogram, raw data sheets& COA) were of TRC-001,TRC-002,TRC-003.
13.	3.2.p.8	Documents for the procurement of API with approval from DRAP (in case of import). Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted these documents.

Decision of 321st meeting of Registration Board:
Deferred for submission of following:

- Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Revised CDP report of drug product, performed against the innovator product.

- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according to the monograph approved by DRAP.
- Analytical method validation report of assay testing of drug product.
- Batch analysis report of all three trial batches of drug, in which all the quality test should be included that are the part of approved monograph of cefixime capsule.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same batches.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Response of the Firm:

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Not Submitted
2.	Analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the Analytical method verification report of drug substance performed by drug product manufacturer.
3.	Revised CDP report of drug product, performed against the innovator product.	Firm submitted the CDP report performed against the Cefim capsule 200mg of M/s. Hilton Pharma.
4.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according to the monograph approved by DRAP.	Submitted in accordance with the monograph approved by DRAP.
5.	Analytical method validation report of assay testing of drug product.	Firm submitted Analytical method validation report of assay testing of drug product.
6.	Batch analysis report of all three trial batches of drug, in which all the quality test should be included that are the part of approved monograph of cefixime capsule.	Firm submitted the batch analysis report of trial batches no. TRC-001, TRC-002, TRC-003.
7.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same batches.	Firm submitted the stability data sheet and chromatograms along raw sheets of trial batches TRC-001, TRC-002, TRC-003. However the audit trial reports also reflects the data of TRS-004,TRS-005 AND TRS-006 and submitted audit trail reports was not in coherence with the chromatograms.
8.	Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in	Firm submitted the sale tax invoice document of lot number CFM1602001,CFM1602002 AND CFM1602003.

	manufacturing of these batches of drug product.	
9.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Submitted
10.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.

Decision of 333rd meeting of Registration Board:
Deferred for clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same batches, since the submitted chromatograms of all three trial batches are not aligned with the audit trail reports.

Response of the Firm:
Firm replied that the "stability batches of cefask 200mg capsules are TRC-001, TRC-002, TRC-003 and the trial batches of Cefask 200mg/5ml suspension are TRS-004, TRS-005, TRS-006. There is a mistake done by the analyst at "0" Month testing. He run both Suspension and capsule stability batches on same method that's why you are seeing both suspension and capsule Trial together in one Audit trail. Later on it's been corrected on "3rd" Month Testing "6th" Month Testing and so on.
Correct Audit trail report along with aligned chromatograms are submitted by the firm.

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

941.	Name, address of Applicant / Marketing Authorization Holder	**M/s Citi Pharma Private Limited**
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10336 dated 22/04/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Cefask DS Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml reconstituted suspension contains: Cefixime as Trihydrate 200mg
	Pharmaceutical form of applied drug	Oral suspension
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin antibiotic

	Reference to Finished product specifications	USP
	Proposed Pack size	1X30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX Suspension USFDA Approved
	For generic drugs (me-too status)	Cefiget 200 mg/5ml Suspension by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefixime drug substance is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36th month Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CFM1602001, CFM1602002, CFM1602003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand REFFERENCE PRODUCT: CEFIGET DS SUSPENSION Manufacturer: GETZ Pharma Batch NO.: 865 MFG Date: 11-2020
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Citi Pharma Private Limited	

	Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur		
API Lot No.	Not mentioned		
Description of Pack (Container closure system)	1 x 30ml (after reconstitution) Filled in amber glass bottle; labelled and packed in standard unit carton provided with leaflet inside.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRS-004	TRS-005	TRS-006
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-2023	08-2023	08-2023
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."	Firm submitted the reply in which it is stated that "As mentioned in section 1.4.2 the analytical methods applied in course of release testing of Cefixime are based on the monograph of Cefixime of USP 42. These methods are followed without any deviation".
2.	3.2. S.4.4	Submit data in section 3.2.S.4.4 as per the guidance document	Firm submitted the COA of three batches of API.

		approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of different batches than that used in the manufacturing of stability batches.	
3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.	Firm has submitted the requisite information.
4.	3.2.S.7	The manufacturing date of API batches was feb,2016 while the approval of cefixime API was granted on 24th July, 2018 by DRAP as evident from the submitted approval letter. Clarify the manufacturing of cefixime API prior grant of approval from DRAP.	In the reply Firm submitted the stability data of different batches of drug substance which were manufactured in October,2018 and having batch no. (CFM1602001, CFM1602002, CFM1602003)
5.	3.2. P.3.1	The bottle fill weight mentioned in section 3.2.P.3.1 is 1266mg while the objective weight per bottle mentioned in process validation report is 6.56mg. Justification is required in this regard.	Firm clarified that 1266mg of suspension powder filled per bottle.
6.	3.2. P.5.1	Justify why weight variation test, test of uniformity of dosage unit and deliverable volume were not included in the specification of drug product.	Firm submitted the specification of drug product in which again not including the weight variation test, test of uniformity of dosage unit and deliverable volume test neither submitted justification.
7.	3.2. P.5.2	Provide complete analytical procedure used for routine testing of drug product, submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm has submitted the copy of USP monograph of cefixime drug substance in section 3.2.P.5.2 instead detailed analytical procedure of cefixime suspension in compliance of USP monograph of cefixime for oral suspension.
8.	3.2. P.5.3	Following observations have been found in the analytical method verification report, clarification is required in this regard: Assay method which has been verified is not in line with USP monograph, justify how the drug product comply with USP specification. How the verification report of cefixime capsule be applied on	Firm did not submit any reply in response of this query.

		cefixime suspension, since the submitted analytical method verification report is of cefixime capsule.	
9.	3.2.P.5.4	Batch analysis report in section 3.2. P.5.4. reflect that filled weight was 65.6 mg ±5% while the COA of drug product on page 263 specified that average weight should be 17.5g±2.5%, justification is required in this regard.	Firm submitted the batch analysis report of three trail batches in which the weight of filled powder varied between 211mg to 213mg, while the average filled weight of powder per bottle in accordance with data given in section 3.2.P.3.1.should be 1266mg.
10.	3.2.P.8	Clarification is required either the dissolution testing is included in the specification of drug product, since the result of dissolution testing was included in the stability data sheets of all three trial batches. Justify for changing the assay limits in the long-term stability data of drug product.	Firm has not submitted any clarification/justification regarding these queries and submitted the new stability data sheet along with supportive documents of trail batches (TRS-004, TRS-005, TRS-006).
11.	3.2.P.8	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm submitted the requisite documents.
12.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import). Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted these documents.

Decision of 321st meeting of Registration Board:

Deferred for submission of following:

- Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Revised CDP report of drug product, performed against the innovator product.

- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according to the USP monograph.
- Analytical method verification report of assay testing of drug product according to the USP monograph of cefixime suspension.
- Clarification regarding the disparity observed in the bottle fill weight both in section 3.2. P.3.1. and 3.2. P.5.4.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same trial batches.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Not Submitted
2.	Analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the Analytical method verification report of drug substance performed by drug product manufacturer.
3.	Revised CDP report of drug product, performed against the innovator product.	Firm submitted the CDP report performed against the product cefspan suspension 200mg/5ml of M/s. Barrett Hodgson.
4.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according to the monograph approved by DRAP.	Submitted in accordance with the monograph approved by DRAP.
5.	Analytical method validation report of assay testing of drug product.	Firm submitted Analytical method validation report of assay testing of drug product.
6.	Clarification regarding the disparity observed in the bottle fill weight both in section 3.2. P.3.1. and 3.2. P.5.4.	Not submitted the reply of this query.
7.	Batch analysis report of all three trial batches of drug, in which all the quality test should be included that are the part of approved monograph of cefixime capsule.	Firm submitted the batch analysis report of trial batches no. TRS-004, TRS-005, TRS-006.
8.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same batches.	Firm submitted the stability data sheet and chromatograms along raw sheets of trial batches TRS-004, TRS-005, TRS-006. However the audit trial reports also reflects the data of TRC-001,TRS-002 AND TRC-003 and submitted audit trail reports was not in coherence with the chromatograms.
9.	Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide	Firm submitted the sale tax invoice document of lot number CFM1602001,CFM1602002 AND CFM1602003.

	documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	
10.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Submitted
11.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.

Decision of 333rd meeting of Registration Board:
Deferred for clarification regarding the trial batches which were actually manufactured for the stability study of applied product and provide the supporting document of same batches, since the submitted chromatograms of all three trial batches are not aligned with the audit trail reports.

Response of the Firm:
Firm replied that the "stability batches of cefask 200mg capsules are TRC-001, TRC-002, TRC-003 and the trial batches of Cefask 200mg/5ml suspension are TRS-004, TRS-005, TRS-006. There is a mistake done by the analyst at "0" Month testing. He run both Suspension and capsule stability batches on same method that's why you are seeing both suspension and capsule Trial together in one Audit trail. Later on it's been corrected on "3rd" Month Testing "6th" Month Testing and so on.
Correct Audit trail report along with aligned chromatograms are submitted by the firm.

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Export Facilitation: Applications was received through letter No.F.1-76/2019-PR-I (EFD)
"M/s Pharmedic Laboratories (Pvt.) Ltd. have achieved benchmark OF USD 1576776.335 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 05 products applications submitted by the firm."

942.	Name, address of Applicant / Marketing Authorization Holder	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Name, address of Manufacturing site.	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2629 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021

	The proposed proprietary name / brand name	Nevol 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..2.5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 2.5mg Tablet by M/s Getz Pharma, Reg. No. 061344
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's , 3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB2.5-TR002	NEB2.5-TR003	NEB2.5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.

		requisite information provided by drug substance manufacturer.	
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:
Deferred for submission of following shortcomings:
Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:
Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.
Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision: Deferred for submission of following:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**
- **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

943.	Name, address of Applicant / Marketing Authorization Holder	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Name, address of Manufacturing site.	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2630 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 5mg Tablet by M/s Getz Pharma, Reg. No. 061345
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process

	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NEB5-TR002, NEB5-TR003, NEB5-TR004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.
API Lot No.	NBB-19070031M
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10’s3x 10’s and 2x 7’s)

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB5-TR002	NEB5-TR003	NEB5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.n	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water conent in the release specification of drug product, since these test are included in the specification of innovator brand.

		Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.

5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision: Deferred for submission of following:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**

• **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**		
944.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.9330 dated 12/04-2022
	Details of fee submitted	PKR 30,000/-: dated 17/03/2022
	The proposed proprietary name / brand name	Nevol 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..10mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Bynevol 10mg Tablet by Atco Laboratories, Reg. No. 081562
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any Pharmacoepia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bynevol 10mg tablet by Atco Laboratories. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bynevol 10mg tablet by Atco Laboratories..…… in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's, 3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB10-TR002	NEB10-TR003	NEB10-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Administrative Portion			
1. Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm

1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80%	Firm claimed that they submitted the updated documents but the submitted analytical

		within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision: Deferred for submission of following:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**
- **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

945	Name, address of Applicant / Marketing Authorization Holder	**M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.**
	Name, address of Manufacturing site.	**M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 18/02/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-43/2006-Lic (Vol-I) dated 10/06/2021. Tablet (general), Capsule (general),Topical/cream/ointment/gel (general), Oral dry powder suspension (Cephalosporin section) and Capsule (Cephalosprin) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No.22772 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 15-05-2023
	The proposed proprietary name / brand name	Diclosaf SR 100MG Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac sodium ..... 100mg.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Pharmaceutical form of applied drug	White to off white sustained release pellets filled in hard gelatin capsules
	Reference to Finished product specifications	BP (Diclofenac Prolonged-release Capsules Diclofenac Prolonged-release Capsules contain Diclofenac Sodium. They are formulated so that the medicament is released over a period of several hours.)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diclofenac sodium 100mg Modified Release capsule (Each capsule contains diclofenac sodium 100mg in a modified release formulation (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets) Glenwood GmbH Pharmazeutische Germany HPRA approved
	For generic drugs (me-too status)	Phologen SR 100mg Capsule (Reg.no.009129) of M/s. Brookes Pharma, Karachi
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of

		excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Phologen SR 100mg Capsule (Reg.no.009129) of M/s. Brookes Pharma, Karachi
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.		
API Lot No.	DE959ER		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR031	TR032	TR033
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings

1.	1.5.2	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.
2.	3.2.S.4.2	Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug substance manufacturer. Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.4.4	Justify for specifying the results of acid resistance stage in the dissolution test of sustained release pellets. COA of drug substance contain note "pellets will remain intact, during buffer stage due to sugar free nature", clarification is required regarding this statement for the sustained release pellets.
5.	3.2.P.1	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of diclofenac sodium SR pellets used 80.40% and 19.60% of empty gelatin shell has taken to make 100%.
6.	3.2.P.5.2	Submit detailed procedure how you have performed uniformity of dosage unit test while quality analysis of drug product. Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug product manufacturer.
7.	3.2.P.6	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.
8.	3.2.P.8	According to the analytical method verification report absorbance value of sample and standard solution was around 0.3 while the obtained absorbance value during assay performance of stability batches were around 0.6, clarify the variation observed in the absorbance value obtained.
9.	2.3.R.1.1	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.

The label claim / formulation of RRA (HPRA) approved formulation is as follows: Difene 100 mg Dual Release Capsule/modified release capsule

Each capsule contains:

Diclofenac sodium 100mg in a modified release formulation (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets)

While firm claimed to comply BP specification. However, in BP available formulation is "Diclofenac Sustained Release capsule" Hence clarification regarding applied specification is required.

 The above mentioned RRA approved formulation contains both type of pellets 25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets) while manufacturing process flow diagram provided by firm revealed that "Neutral pellets /drug pellets prepared by extrusion Spheronization loaded into Fluid bed Bottom/Wruster coater drug layering is done by using solution or suspension that is sprayed by peristaltic pump with hot air stream generating dry and highly spherical particles After Drug lavering Seal coating. Delayed Release/Entenc coating done through this technique Similarly Sustained Release Modified release/Extended release and immediate release Coating generally employed to improve the dissolution rates and hence improve the bioavailability of poorly soluble drugs Screening is done on the final product, such as particle size and size distribution, other physical parameter also checked such as bulk density, moisture content."

Hence it is evident that contrary to RRA approved formulation whole proportion of Drug was formulated to be sustained release and delayed release (by way of enteric coating) simultaneously. Hence applied formulation need to be justified in light of RRA approved formulation. Furthermore, following drug release pattern need to be justified accordingly:

- Acid medium (0.1 M HCl)
- NMT 10% 0.1 M HCl after 120 min
- Buffer medium (pH 6.8)
- 30-65% of labelled amount of Diclofenac sodium pellets should be released after 3 hours
- NLT 70% of labelled amount of Diclofenac sodium pellets should be released after 8 hours

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.	Firm submitted the amended label claim without the requisite fee: Each capsule contains: Diclofenac Sodium SR pellets equivalent to Diclofenac sodium…100mg
2.	Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug substance manufacturer.	Firm in their reply stated that "Either sustained release pellets or Delayed release pellets, these have to pass from acid medium, its interval is about from 30 minutes to 2 hours, to review pellets behaviour its dissolution in acid medium is verified.
3.	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
4.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
5.	Justify for specifying the results of acid resistance stage in the dissolution test of sustained release pellets. COA of drug substance contain note "pellets will remain intact, during buffer stage due to sugar free nature", clarification is required regarding this statement for the sustained release pellets.	Firm replied that "Either sustained release pellets or Delayed release pellets, these have to pass from acid medium, its interval is about from 30 minutes to 2 hours, to review pellets behaviour its dissolution in acid medium is verified".
6.	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of diclofenac sodium SR pellets used 80.40% and 19.60% of empty gelatin shell has taken to make 100%.	Firm submitted the amended master formulation table with the claim that there is no role of hard gelatin capsule in potency adjustment.
7.	Submit detailed procedure how you have performed uniformity of dosage unit test while quality analysis of drug product.	In their reply firm submitted the content of general chapter of USP ⟨905⟩ UNIFORMITY OF DOSAGE UNIT instead of submitting the actual procedure of uniformity of dosage unit test adopted by the firm.
8.	Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug product manufacturer.	Firm replied that BP monograph for Diclofenac SR pellets states that follow the manufacturer specs. Our source for Diclofenac SR pellets is vision pharma, they include acid resistance stage in dissolution test, so, we follow them. However, the BP monograph of Diclofenac Prolonged-release Capsules stated that "Diclofenac prolonged release capsule from different manufacturer, whilst complying with the requirements of the monograph, are not interchangeable unless otherwise justified and authorized.
9.	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard	In their reply firm stated that the quality parameters of DICLOFENAC SODIUM in both BP and USP are same so they used USP reference standard for testing of BP complied product.

	when they are supplied in house specified diclofenac sodium pellets.	
10.	According to the analytical method verification report absorbance value of sample and standard solution was around 0.3 while the obtained absorbance value during assay performance of stability batches were around 0.6, clarify the variation observed in the absorbance value obtained.	Firm replied that final concentration was not same, double final concentration double absorbance found. They performed the method verification with 20µg/ml. However, the reply is in contradiction to the observed value of absorbance i.e. the obtained absorbance value in verification report was around 0.3 while the obtained absorbance value during assay performance of stability batches were around 0.6. Further, the assay procedure adopted for verification studies is also not in accordance with BP monograph.
11.	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.	Submitted

Decision: Deferred for submission of following:

- **Submit the reference of applied formulation either the drug product complied BP specification (Diclofenac Prolonged-release Capsules) or the composition of capsule is in accordance with reference product i.e. Each capsule contains: Diclofenac sodium 100mg in a modified release formulation (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets).**
- **Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.**
- **According to the analytical method verification report absorbance value of sample and standard solution was around 0.3 while the obtained absorbance value during assay performance of stability batches were around 0.6, clarify the variation observed in the absorbance value obtained.**
- **The assay procedure adopted for verification studies is also not in accordance with BP monograph, clarification is required in this regard.**

946	Name, address of Applicant / Marketing Authorization Holder	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Name, address of Manufacturing site.	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 18/02/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-43/2006-Lic (Vol-I) dated 10/06/2021. Tablet (general), Capsule (general),Topical/cream/ointment/gel (general), Oral dry powder suspension (Cephalosporin section) and Capsule (Cephalosporin) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No.22771 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 15-05-2023
	The proposed proprietary name / brand name	Diclosaf 50mg Capsule

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac sodium ..... 50mg.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in hard gelatin capsules
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HPRA Ireland approved Difene 50mg Capsule by Glenwood GmbH Germany.
	For generic drugs (me-too status)	Phologen 50mg Capsule (Reg.no.009128) of M/s. Brookes Pharma, Karachi
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Mobikare 50 Capsules of M/s. Barret & Hodgson Pakistan (Batch no. D3560)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan. (Diclofenac sodium enteric coated pellets (33%)
API Lot No.	DE617

Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR025	TR026	TR027
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.5.2	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.
2.	3.2.S.4.2	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.1	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of diclofenac sodium EC pellets used 75.88% and 24.12% of empty gelatin shell has taken to make 100%.
5.	3.2.P.5.2	Submit detailed procedure how you have performed uniformity of dosage unit test while quality analysis of drug product.
6.	3.2.P.6	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.
7.	2.3.R.1.1	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.

Decision of 333rd meeting of Registration Board:

Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the Firm:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the firm
1.	1.5.2	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.	Firm submitted the revised label claim without the requisite fee: Each hard gelatin capsule contains: Diclofenac sodium enteric coated pellets equivalent to Diclofenac sodium…50mg
2.	3.2.S.4.2	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
4.	3.2.P.1	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of diclofenac sodium EC pellets used 75.88% and 24.12% of empty gelatin shell has taken to make 100%.	Firm replied that they used Diclofenac sodium 33% EC pellets and adjusted the potency 100% with these EC pellets. For 100% potency of diclofenac sodium, 151.5mg EC 33% pellets should be used we are taking 151.5mg of Diclofenac EC pellets in a capsule.
5.	3.2.P.5.2	Submit detailed procedure how you have performed uniformity of dosage unit test while performing the quality analysis of drug product.	In their reply firm submitted the content of general chapter of USP ⟨905⟩ UNIFORMITY OF DOSAGE UNIT instead of submitting the actual procedure of uniformity of dosage unit test adopted by the firm.
6.	3.2.P.6	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.	In their reply firm stated that the quality parameters of DICLOFENAC SODIUM in both BP and USP are same so they used USP reference standard for testing of BP complied product.
7.	2.3.R.1.1	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.	Submitted

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

947.	Name, address of Applicant / Marketing Authorization Holder	**M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur**
	Name, address of Manufacturing site.	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	afresh license granted on 10/11/2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26128 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- Dated 26-10-2023
	The proposed proprietary name / brand name	PTL Tablet 40mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric coated tablet contains: Pantoprazole as sodium sequihydrate…40mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Pharmaceutical form of applied drug	White to off white circular round enteric coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Neege 40mg Tablet by M/s Searle Pakistan, Reg. No. 110185
	Name and address of API manufacturer.	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andra pardesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. Firm has submitted CDP results of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andrapardesh, India.		
API Lot No.	NA		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA-PT-001	MA-PT-002	MA-PT-003
Batch Size	550 Tablets	550 Tablets	550 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate no. WC-0494 issuing date 26-02-2021 and valid until three years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
2.	3.2.S.4.3	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
4.	3.2.S.7	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.
5.	3.2.P.1	Justify the formulation which is different in terms of qualitative composition from that of innovator product.
6.	3.2.P.2.2.1	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
7.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Not submitted
2.	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Not submitted
3.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Not submitted

4.	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.	submitted
5.	Justify the formulation which is different in terms of qualitative composition from that of innovator product.	Not submitted
6.	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.	Not submitted
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
8.	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted

Decision: Deferred for submission of following:

- **Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."**
- **Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.**
- **Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.**
- **Justify the formulation which is different in terms of qualitative composition from that of innovator product.**
- **Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.**
- **Documents for the procurement of API with approval from DRAP (in case of import).**
- **Compliance Record of HPLC software 21CFR & audit trail reports on product testing**

948.	**Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.**	
	Name, address of Applicant / Marketing Authorization Holder	M/s. World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.
	Name, address of Manufacturing site.	M/S World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale

		☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.706 : dated 09-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 67913763 dated 03-01-2023.
	The proposed proprietary name / brand name	SetBiz 5mg/5ml syrup.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cetirizine dihydrochloride 5mg (B.P Specifications)
	Pharmaceutical form of applied drug	Oral liquid.
	Pharmacotherapeutic Group of (API)	R06AE07 Antihistamine
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	60ml,90ml,120ml,450ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA APPROVED
	For generic drugs (me-too status)	Citzin Syrup, NovaMed Pharmaceuticals, Reg. No. 063620.
	GMP status of the Finished product manufacturer	New license issued dated 14-09-2021 w.e.f. 13-09-2021.
	Name and address of API manufacturer.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.
	Module-II (Quality Overall Summary)	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.
	Module III (Drug Substance)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Stability studies	Official monograph of Cetirizine Hydrochloride is present in B.P. Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months.

		The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. Batches:(CZ/V/00411,CZ/V/00511& CZ/V/00611)
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Pharmaceutical Equivalence is established against the Citzin syrup manufactured by NovaMed pharmaceuticals Lahore by performing quality tests (Identification, filled volume, leakage teat, pH and Assay). Results of both the products are similar. CDP is not applicable.

STABILITY STUDY DATA			
Manufacturer of API	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.		
API Lot No.	CTZ03521		
Description of Pack (Container closure system)	An amber glass bottle containing an-off white colored syrupy liquid with pleasant flavour, sealed with aluminum pp cap and packed in specific unitcarton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-CS-001	RD-CS-001	RD-CS-001
Batch Size	500 bottles.	500 bottles.	500 bottles.
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	28-09-2022.	28-09-2022.	28-09-2022.
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of approval of PolyBiz syrup in 322 minutes of meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate #L.Dis.No:82408/TS/2022 issued by Drug Control Administration Government of Telangana issued on 15-03-2022and valid until 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that the cetirizine dihydrochloride material of quantity 500g was obtained via loan from British Pharmaceuticals Lahore. Copy of documents already submitted in DRAP on dated 14-02-2023. Copy of Form 3, 5 ,7 from & invoice (invoice# ZHI-CI/5465/0621) dated: 26-06-2021 cleared by DRAP Lahore office dated 12-07-2021

		specifying import 100Kg Cetirizine 2HCl(Batch# CTZ03521)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.7	Justify for not including the test of pH determination and loss on drying test while performing the stability studies of drug substance.
2.	3.2.P.1	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
3.	3.2.P.2.2.1	Justify for performing the pharmaceutical equivalence against the comparator product instead of brand leader/ innovator / reference product.
4.	3.2. P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.
5.	3.2.P.5.2	Justify for not adopting the assay procedure as recommended in BP monograph of Cetirizine Oral solution, since the conc. of sample and standard solution specified in the assay method is different from the concentrations of solution mentioned in BP. Further the validation studies were also performed keeping the conc. of sample and standard solution 0.1% while BP recommends 0.002% conc. for both solutions in assay testing, then justify how the method comply BP specification.
6.	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data. Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision of 327th meeting of Registration Board:

Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	3.2.S.7	Justify for not including the test of pH determination and loss on drying test while performing the stability studies of drug substance.	Firm replied that pH and Loss on Drying test is included in the specification and routine testing but by the manufacturer this test was skipped during stability studies of drug substance.
2.	3.2.P.1	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted preservative effectiveness test report.

3.	3.2.P.2.2 .1	Justify for performing the pharmaceutical equivalence against the comparator product instead of brand leader/ innovator / reference product.	Firm replied that comparative product sample was available at that time of trial batch manufacturing, so they use that sample for pharmaceutical equivalence.
4.	3.2. P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.	COAs of propylene glycol and sorbitol in which results of impurity test of DEG and EG is included.
5.	3.2.P.5.2	Justify for not adopting the assay procedure as recommended in BP monograph of Cetirizine Oral solution, since the conc. of sample and standard solution specified in the assay method is different from the concentrations of solution mentioned in BP. Further the validation studies were also performed keeping the conc. of sample and standard solution 0.1% while BP recommends 0.002% conc. for both solutions in assay testing, then justify how the method comply BP specification.	Firm replied that "All chromatographic conditions as described in BP monograph was followed for the testing of product, sample and standard concentration was set for the easiness for the analyst and method was verified on the same concentration was set for the easiness for the analyst and method was verified on the same concentration as well.
6.	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	Submitted
7.	Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Firm submitted the copy of letter by DCA (Government of Telangana) in which it is certified that License No. 40/MD/AP/2012/B/G renewed 18/10/2022 and validity would get expired by 17/10/2027.

Decision of 333rd meeting of Registration Board:

Deferred for submission of following shortcomings:

Scientific justification for not performing critical tests of pH determination and loss on drying loss on drying during the stability studies.

Justify for not performing the assay of drug product in accordance with BP monograph of Cetirizine Oral solution.

Response of the Firm:

Scientific justification for not performing critical tests of pH determination and loss on drying during the stability studies.

Firm submitted the revised stability data of drug substance including the test of pH determination and loss on drying.

Justify for not performing the assay of drug product in accordance with BP monograph of Cetirizine Oral solution.

Firm submitted the revised analytical procedure of drug product in accordance with BP monograph along with performance report at 16 month of stability study.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
949.	Name, address of Applicant / Marketing Authorization Holder	Medicraft Pharmaceuticals (Pvt) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Name, address of Manufacturing site.	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Evidence of approval of manufacturing facility	Firm submitted the copy of letter of Licensing Division regarding the grant of additional section of dry powder for Injection (Carbapenem) dated 14th October,2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5 Dy.No 7653 dated 30-05-2019 Rs.20,000/- dated 30-05-2019 Form-5F Dy.No 14522 dated 08-08-2019 Form-5F Dy.No 32154 dated 24-11-2021
	Details of fee submitted	PKR 20,000/-: dated 30-05-2019
	The proposed proprietary name / brand name	Medipenem 500mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (MERREM 500mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 500mg Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 500mg Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site: No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the product Meronem Injection 500mg of M/s. Pfizer Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.		
API Lot No.	8MT2102165		
Description of Pack (Container closure system)	Type I glass vial of 20ml packed inunit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ME01	ME02	ME03
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	03-2021	03-2021	03-2021

Date of Initiation	17-03-2021	17-03-2021	24-03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer (M/s. Medicraft Pharmaceuticals (Pvt.) Ltd.)"	submitted
2.	Validation of analytical procedures Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. Batch Analysis Report	Submitted
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Firm submitted the batch analysis report of drug substance by drug product manufacturer.
4.	Submit real time stability study data of three batches of the drug substance as per the conditions of zone IV-A since the submitted stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5%.	Not submitted
5.	Submit data in section 3.2.P.2.1.2 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function	Firm submitted the requisite details of section 3.2.P.2.1.2.

	of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications). *Overages are not acceptable unless fully justified* If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").	
6.	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	Firm submitted the information related to the diluents.
7.	Provide information specify the justification of formulation and method of manufacturing. It is important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall also be discussed.	submitted
8.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	submitted
9.	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted Pharmaceutical equivalence report performed against the product Meronem Injection of M/s. Pfizer Pharmaceuticals.
10.	Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Firm submitted the requisite details.
11.	Submit data in section 3.2.P.2.2.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "*The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".*	Submitted
12.	Justify the use of 10ml type-II glass vial for the applied drug product since as per the innovator's product Meropenem for injection is supplied in 20 mL and 30 mL injection vials	Firm submitted the reply that 20ml glass vial is used for 500mg and 30ml is used for 100mg.

	containing sufficient meropenem to deliver 500 mg or 1 gram for intravenous administration, respectively.	
13.	Provide the composition for the drug substance with clearly indicated the quantity of its base form and quantity of sodium carbonate along with the amount of sodium (as is basis).	Submitted
14.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	Submitted the master formulation.
15.	Provide control of critical steps and intermediates for the applied drug product in section 3.2.P.3.4, since the submitted document contains various variation in terms of weight and fill volume and does not cover all the critical steps involved in the manufacturing.	Submitted the requisite information of section 3.2.P.3.4.
16.	• Variation has been observed regarding the sterilization process of vial in the process validation protocol. Clarification is required either the dry heat has been used for sterilization of vials or sterilized in autoclave. • The process validation protocols did not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard. • The process validation protocols did not define any critical steps, justify how your process validation protocols can be considered acceptable. • In process validation protocol container description specified that Type-I 2ml clear glass vial has been used clarification is required regarding the variation of container closure system of the applied product. • According to the process validation data sheet bulk solution has been prepared after mixing in manufacturing tank while the manufacturing process given in previous sections revealed that ready to fill active material has been imported and only filling of active material in their respective container has been done by drug product manufacturer clarification is required regarding this variation of manufacturing procedure.	Firm submitted the revised process validation protocol.
17.	• Justify why the test of content of sodium and loss on drying is not mentioned in the specifications of the drug product • Justification is required for including volume variation test in the dry powder injectable product specification.	Firm submitted the revised specification of drug product in which test of content of sodium and loss on drying is included. Further claimed that they follow USP specification for drug product.

	• In section 1.5.6 applicant claimed USP specification for drug product while in - house specification has been claimed in section 3.2.P.5.2 clarification is required in this regard.	
18.	As per the submitted master formulation 1000mg per vial quantity has been filled while the weight variation limit specified is 1.445gm±3% per vial justification is required regarding the disparity in filled weight of active material.	Firm submitted the revised master formulation along with calculation of filled weight.
19.	• As per the submitted procedure of assay, sample solution has been prepared in mobile phase in which 50mg of meropenem has been dissolved initially while according to the USP "*Constitute a container of Meropenem for Injection with a volume of water corresponding to the quantity of solvent specified in the labeling, and dilute with water".* Justify how your method could be considered as complying with USP monograph. • The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph. • Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer. • Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm submitted the revised analytical procedure in compliance of USP monograph of Meropenem Injection.
20.	• Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. • Provide the data of verification studies along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Submitted
21.	Scientific justification for not performing the test of sodium content and loss on drying for the analysis of all three batches of drug product.	Firm submitted the batch analysis report
22.	As per the batch analysis certificate manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while the section approval was granted on 14th October, 2020.Clarification is required regarding the manufacturing of batches prior section approval, further specify where the manufacturing of these batches was	Firm did not clarify the manufacturing dates of trial batches , since, initially the manufacturing date of trial batches of both 500mg and 1000mg was the year 2019, later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.

	carried out.	
23.	Provide COA of primary / secondary reference standard including source and lot number.	submitted
24.	Stability Following clarification is required regarding the date of manufacturing of batches for product development and stability studies: • As per the batch analysis certificate, manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while as per stability data sheets same batches has been manufactured on MP01: 03-2021, MP02:04-2021, MP03:05-2021.Clarification is required in this regard.	Firm clarified that the trial batches of 500mg is ME-01,ME-02,ME-03,while the trial batches of 1000mg is MP-01,MP-02,MP-03.
25.	Justify why the test of content of sodium and loss on drying has not been performed during the stability studies of drug product.	Firm submitted the revised stability data in which both of these tests are included.
26.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Not submitted
27.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Submitted
28.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
29.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
30.	• Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
31.	Executed Production Documents Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted

Decision of 331st meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.
- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Response of the Firm:

- **Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.**

Firm submitted the stability data of three batches of the drug substance as per the zone IV-a conditions.

- **Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.**

Firm replied that in 2019 their carbapenem section was ready for inspection but the inspection process of our section was under process and during this period we got the raw material on loan basis and processed our trial batches. Later, they were told that it will not be approved because they don't have a section approval letter and proof of import is also required, so they stopped the work on previous trial batches and initiated new studies after the section approval. After section approval we imported the raw material from Shenzhen Haibin Pharmaceuticals China, via DHL.

Further firm claimed that the old stability documents were withdrawn and previous working was nullified so they used the same batch number ME01, ME02, ME03 for 500mg of their new trial batches.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Firm replied that the Batch no. 8MT2102165 is used in all three batches of finished product stability, which was imported from China via DHL and DHL invoice has been submitted by the Firm.

The DHL invoices submitted by the firm were not verifiable.

Decision of 333rd meeting of Registration Board:

Deferred for evidence of procurement/import of drug substance with approval of DRAP I&E Office, since the submitted DHL courier receipt is not verifiable.

Reply of the Evaluator:

M/s Medicraft Pharmaceutical Pvt. Ltd Peshawar has submitted original letter from DHL Express Islamabad which states as under:

"Dear customer,

It is to inform you that we have received your request to verify consignment details. Please note that we only retain tracking record for last 3 months and after six months Airway bill numbers are reused for consignment anywhere in the world. We retain very limited details for old consignment and after checking we can confirm that the provided details of consignment are correct. It was a consignment delivered in Peshawar in year 2021. Consignment Airways Bill number was 2867971820 and its origin was China. Consignor of the consignment was Shenzhen Haibin Pharmaceutical Co. and was consigned to Medicraft Pharmaceuticals Pvt. Ltd. Delivery of consignment was made in Peshawar City. Declared contents of the consignment were ***Meropenem****.*

Unfortunately, we have no further details available in the system and that we are not authorized by global teams to stamp old Airway bills.

We hope this response is sufficient and will conclude the matter."

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

950.	Name, address of Applicant / Marketing Authorization Holder	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Name, address of Manufacturing site.	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Evidence of approval of manufacturing facility	Firm submitted the copy of letter of Licensing Division regarding the grant of additional section of dry powder for Injection (Carbapenem) dated 14th October,2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5 Dy. No 7654 dated 30-05-2019 Rs. 20,000/- dated 30-05-2019 Form-5F Dy. No 14521 dated 08-08-2019 Form-5F Dy.No 32155 dated 24-11-2021
	Details of fee submitted	PKR 20,000/-: dated 30-05-2019
	The proposed proprietary name / brand name	Medipenem 1000mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……1000mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (MERREM 1000mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 1000mg Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 1000mg Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian District, Shenzhen City, Guangdong Province, People's Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the product Meronem Injection 500mg of M/s. Pfizer Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyang Road, Yantian District, Shenzhen City, Guangdong Province, People's Republic of China.		
API Lot No.	8MT2102165		
Description of Pack (Container closure system)	Type I glass vial of 20ml packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MP01	MP02	MP03
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	24-03-2021	24-03-2021	24-03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like	submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer (M/s. Medicraft Pharmaceuticals (Pvt.) Ltd.)"	submitted
2.	Validation of analytical procedures Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. Batch Analysis Report	Submitted
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Firm submitted the batch analysis report of drug substance by drug product manufacturer.
4.	Submit real time stability study data of three batches of the drug substance as per the conditions of zone IV-A since the submitted stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5%.	Not submitted
5.	Submit data in section 3.2.P.2.1.2 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications). *Overages are not acceptable unless fully justified* If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").	Firm submitted the requisite details of section 3.2.P.2.1.2.
6.	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent	Firm submitted the information related to the diluents.

	which is to be provided along with the applied drug.	
7.	Provide information specify the justification of formulation and method of manufacturing. It is important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall also be discussed.	submitted
8.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	submitted
9.	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted Pharmaceutical equivalence report performed against the product Meronem Injection of M/s. Pfizer Pharmaceuticals.
10.	Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Firm submitted the requisite details.
11.	Submit data in section 3.2.P.2.2.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "*The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".*	Submitted
12.	Justify the use of 10ml type-II glass vial for the applied drug product since as per the innovator's product Meropenem for injection is supplied in 20 mL and 30 mL injection vials containing sufficient meropenem to deliver 500 mg or 1 gram for intravenous administration, respectively.	Firm submitted the reply that 20ml glass vial is used for 500mg and 30ml is used for 100mg.
13.	Provide the composition for the drug substance with clearly indicated the quantity of its base form and quantity of sodium carbonate along with the amount of sodium (as is basis).	Submitted
14.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	Submitted the master formulation.

15.	Provide control of critical steps and intermediates for the applied drug product in section 3.2.P.3.4, since the submitted document contains various variation in terms of weight and fill volume and does not cover all the critical steps involved in the manufacturing.	Submitted the requisite information of section 3.2.P.3.4.
16.	• Variation has been observed regarding the sterilization process of vial in the process validation protocol. Clarification is required either the dry heat has been used for sterilization of vials or sterilized in autoclave. • The process validation protocols did not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard. • The process validation protocols did not define any critical steps, justify how your process validation protocols can be considered acceptable. • In process validation protocol container description specified that Type-I 2ml clear glass vial has been used clarification is required regarding the variation of container closure system of the applied product. • According to the process validation data sheet bulk solution has been prepared after mixing in manufacturing tank while the manufacturing process given in previous sections revealed that ready to fill active material has been imported and only filling of active material in their respective container has been done by drug product manufacturer clarification is required regarding this variation of manufacturing procedure.	Firm submitted the revised process validation protocol.
17.	• Justify why the test of content of sodium and loss on drying is not mentioned in the specifications of the drug product • Justification is required for including volume variation test in the dry powder injectable product specification. • In section 1.5.6 applicant claimed USP specification for drug product while in - house specification has been claimed in section 3.2.P.5.2 clarification is required in this regard.	Firm submitted the revised specification of drug product in which test of content of sodium and loss on drying is included. Further claimed that they follow USP specification for drug product.
18.	As per the submitted master formulation 1000mg per vial quantity has been filled while the weight variation limit specified is 1.445gm±3% per vial justification is required regarding the disparity in filled weight of active material.	Firm submitted the revised master formulation along with calculation of filled weight.

19.	• As per the submitted procedure of assay, sample solution has been prepared in mobile phase in which 50mg of meropenem has been dissolved initially while according to the USP "*Constitute a container of Meropenem for Injection with a volume of water corresponding to the quantity of solvent specified in the labeling, and dilute with water".* Justify how your method could be considered as complying with USP monograph. • The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph. • Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer. • Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm submitted the revised analytical procedure in compliance of USP monograph of Meropenem Injection.
20.	• Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. • Provide the data of verification studies along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Submitted
21.	Scientific justification for not performing the test of sodium content and loss on drying for the analysis of all three batches of drug product.	Firm submitted the batch analysis report
22.	As per the batch analysis certificate manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while the section approval was granted on 14th October, 2020.Clarification is required regarding the manufacturing of batches prior section approval, further specify where the manufacturing of these batches was carried out.	Firm did not clarify the manufacturing dates of trial batches , since, initially the manufacturing date of trial batches of both 500mg and 1000mg was the year 2019, later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.
23.	Provide COA of primary / secondary reference standard including source and lot number.	submitted
24.	Stability Following clarification is required regarding the date of manufacturing of batches for product development and stability studies: • As per the batch analysis certificate, manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while as per stability data	Firm clarified that the trial batches of 500mg is ME-01,ME-02,ME-03,while the trial batches of 1000mg is MP-01,MP-02,MP-03.

	sheets same batches has been manufactured on MP01: 03-2021, MP02:04-2021, MP03:05-2021.Clarification is required in this regard.	
25.	Justify why the test of content of sodium and loss on drying has not been performed during the stability studies of drug product.	Firm submitted the revised stability data in which both of these tests are included.
26.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Not submitted
27.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Submitted
28.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
29.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
30.	• Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
31.	Executed Production Documents Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted

Decision of 331st meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.
- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Response of the Firm:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.

Firm submitted the stability data of three batches of the drug substance as per the zone IV-a conditions.

- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.

Firm replied that in 2019 their carbapenem section was ready for inspection but the inspection process of our section was under process and during this period we got the raw material on loan basis and processed our trial batches. Later, they were told that it will not be approved because they don't have a section approval letter and proof of import is also required, so they stopped the work on previous trial batches and initiated new studies after

the section approval. After section approval we imported the raw material from Shenzhen Haibin Pharmaceuticals China, via DHL.
Further firm claimed that the old stability documents were withdrawn and previous working was nullified so they used the same batch number MP01, MP02, MP03 for 1000mg of their new trial batches.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Firm replied that the Batch no. 8MT2102165 is used in all three batches of finished product stability, which was imported from China via DHL and DHL invoice has been submitted by the Firm.

Decision of 333rd meeting of Registration Board:
Deferred for evidence of procurement/import of drug substance with approval of DRAP I&E Office, since the submitted DHL courier receipt is not verifiable.

Reply of the Evaluator:
M/s Medicraft Pharmaceutical Pvt. Ltd Peshawar has submitted original letter from DHL Express Islamabad which states as under:
"Dear customer,
It is to inform you that we have received your request to verify consignment details. Please note that we only retain tracking record for last 3 months and after six months Airway bill numbers are reused for consignment anywhere in the world. We retain very limited details for old consignment and after checking we can confirm that the provided details of consignment are correct. It was a consignment delivered in Peshawar in year 2021. Consignment Airways Bill number was 2867971820 and its origin was China. Consignor of the consignment was Shenzhen Haibin Pharmaceutical Co. and was consigned to Medicraft Pharmaceuticals Pvt. Ltd. Delivery of consignment was made in Peshawar City. Declared contents of the consignment were ***Meropenem****.*
Unfortunately, we have no further details available in the system and that we are not authorized by global teams to stamp old Airway bills.
We hope this response is sufficient and will conclude the matter."

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Central Licensing Board in 278th meeting held on 10th &11th December,2020 has considered and approved additional section "Liquid Ampoule (SVP) General Section" of M/s Islam Pharmaceuticals, Sialkot.

951.	Name, address of Applicant / Marketing Authorization Holder	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section for liquid ampoule (SVP) General was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020
	Evidence of approval of manufacturing facility	New Section for liquid ampoule (SVP) General was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 22726 Dated: 11/08/2022
	Details of fee submitted	PKR 30,000/- Dated: 02/12/2021
	The proposed proprietary name / brand name	Diflo 75mg/3ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Diclofenac Sodium …….75mg
	Pharmacotherapeutic Group of (API)	Clear and colorless solution filled in clear glass ampoules
	Pharmaceutical form of applied drug	Non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	3ml×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Econac Injection 75mg/3ml, MHRA Approved.
	For generic drugs (me-too status)	Voren injection 75mg/3ml by Asian Continental (Pvt.) Ltd. Reg. No. 007737
	Name and address of API manufacturer.	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, china.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches:(1702201,1702202, 1702203)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Voren injection 75mg/3ml injection by Asian Continental Pvt. Ltd. by performing quality tests

		(Appearance, Identification, Assay, pH and Volume Variation). All parameters results are in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, china.		
API Lot No.	2010205		
Description of Pack (Container closure system)	USP Type-I Clear Glass ampoules in PVC Tray, packed in unit carton (3ml×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21ARn048	21ARn048	21ARn048
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	24-05-2021	24-05-2021	24-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. (New Section)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SN20190340 issued by CFDA valid till 24/02/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.14850/2020/DRAP-AD-VIII (I&E) dated 16/10/2020 is submitted wherein the permission to import different APIs including Diclofenac sodium for the purpose of test/analysis and stability studies is granted. • AirWay Bill No.607PVG91267326 Dated 22/12/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings

1.	3.2.S.4.4	Justify for not importing/using the sterile API for manufacturing of injection, since the results of sterility test and Bacterial Endotoxin test is not included in the COA of drug substance by both drug substance manufacturer and drug product manufacturer.
2.	3.2.P.1	• Clarify the role of benzyl alcohol in the applied formulation. • According to the literature of innovator brand the recommended quantity of Sodium metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the quantity of both excipients used in the applied formulation is different from the recommended quantity by the innovator, scientifically rationalize the quantity of both excipients used in the applied formulation.
3.	3.2.P.2.2.1	Justify for not performing the test of osmolality, particulate matter,sterility and Bacterial Endotoxin test while establishing the pharmaceutical equivalence against the reference product.
4.	3.2.P.3.3	Justify for prefering the aseptic filling procedure over terminal sterilization in the manufacturing procedure of drug product.
5.	3.2.P.5.1	• Submit reference of specification of pH test. • Justify for not including the test of osmolality in the finished product specification since it is the critical parameter in the injectable formulation.
6.	3.2.P.8	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Clarify the volume of glass ampoule use for primary packaging of drug product, since it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.
7.	2.3.R.1.1	Submit minimum handling capacity of the equipment used in the formulation of trail batches.

Decision of 327th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify for not importing/using the sterile API for manufacturing of injection, since the results of sterility test and Bacterial Endotoxin test is not included in the COA of drug substance by both drug substance manufacturer and drug product manufacturer. Firm replied that "since applied product is liquid injection and to be manufactured through aseptic filling procedure (sterilization through filtration method) so it is not necessary to use sterile API. However, Reference of USP general test <1211> sterility assurance stated that *The preparation of sterile products encompass a wide range of materials including active pharmaceutical ingredients (small and large molecules), excipients, solvents (usually water), process gases and processing aids, all of which contribute to the microbiological quality attributes of the product. Depending upon the product being manufactured, this can require consideration of bacterial, endotoxin, and particulate contamination. Specific microbiological quality testing requirements for inactive and active ingredients testing is often specified in a relevant USP–NF monograph. Requirements for microbiological testing for total aerobic bacteria, yeast and mold counts, and specified organisms are given in Microbial Enumeration Tests and Tests for Specified Microorganisms, and the recommended but non-mandatory enumeration targets for microbiological testing are given in Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use. Some specific products may require other testing for specified organisms, including viruses, as a requirement of their regulatory approval. Requirements for bacterial endotoxin testing in injectable products are covered, which describes qualification of Limulus amebocyte lysate testing for acceptable levels of bacterial endotoxin. Raw material specifications must be appropriate to ensure that the manufacturing process consistently results, as demonstrated through process validation, in products conforming to the microbiological critical quality attributes.*		
2.	3.2.P.1	Clarify the role of benzyl alcohol in the applied formulation.	Firm replied that "Benzyl alcohol is used as solvent (to enhance the solubility of drug substance) reference Handbook of pharmaceutical excipients 7th Edition by

			RayMond C Rowe a. It is also the part of innovator formulation. In literature of "Voltarol injection" which is MHRA approved, only the qualitative composition of injection is given and it does not mention quantities of excipients reference document is attached as annexure-IB.
3.	3.2.P.1	According to the literature of innovator brand the recommended quantity of Sodium metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the quantity of both excipients used in the applied formulation is different from the recommended quantity by the innovator, scientifically rationalize the quantity of both excipients used in the applied formulation.	Firm replied that in literature of "Voltarol injection" which is MHRA approved, only the qualitative composition of injection is given and it does not mention quantities of excipients. As per FDA document, limit of inactive ingredients for approved drug products, the maximum limit of benzyl alcohol in intramuscular injection is 144 mg and in our formulation it is 126mg. Limit of sodium metabisulphite is 40mg and in our formulation it is 9.98mg. *However, the USFDA Inactive ingredient database do not mentioned the maximum potency per unit dose of benzyl alcohol and sodium metabisulphite in the IM/IV liquid injection.*
4.	3.2.P.2.2.1	Justify for not performing the test of osmolality, particulate matter,sterility and Bacterial Endotoxin test while establishing the pharmaceutical equivalence against the reference product.	Firm replied that *All the tests including sterility, bacterial endotoxin, particulate matter were performed (mentioned in report under section 3.2.P.5.4 batch analysis) but were not added to pharmaceutical equivalence report. Pharmaceutical equivalence study report containing test results for particulate matter, Bacterial Endotoxin and sterility test* is submitted.
5.	3.2.P.3.3	Justify for preferring the aseptic filling procedure over terminal sterilization in the manufacturing procedure of drug product.	Firm replied that "*According to an article published in Journal of Pharmaceutical Sciences, Vol. 90, 541-544 (2001) Wiley-Liss, Inc. and the American Pharmaceutical Association, "A known impurity "1-(2,6-diclorophenyl) indolin-2-one" is formed in the production of a parenteral dosage form of Diclofenac sodium if terminally sterilized by autoclave" research article is attached as annexure-III".* Due to above reason we preferred aseptic filling over terminal sterilization.
6.	3.2.P.5.1	Submit reference of specification of pH test.	Firm replied that "At the time of product development we searched for reference of pH but did not found any authentic document, then we tested different brands of diclofenac sodium injection and found the pH around 8.3, so we set 8.3 as our target pH and adjusted the limits ± 0.5 of target pH (Limit: 7.8 – 8.8). Later on we got another reference "Handbook of Pharmaceutical

			Manufacturing Formulations Sterile Products" by Sarfaraz K. Niazi, Pharmaceutical Scientist, Inc. Deerfield, Illinois, USA, published in 2009 which gives the range of pH of diclofenac sodium injection from 8.0 – 9.0. Initial results of our stability batches and after 03 and 06-month stability studies are well within the limit which is given in above mentioned book.
7.	3.2.p.5.1	Justify for not including the test of osmolality in the finished product specification since it is the critical parameter in the injectable formulation.	Firm replied that "Osmolality test was performed on product development stage so it was not reported in finish product specification. Osmolality test results and revised finish product specifications after addition of osmolality test are submitted".
8.	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	Stability data for 03 and 06 month of drug product was submitted by the firm.
9.	3.2.P.8	Clarify the volume of glass ampoule use for primary packaging of drug product, since it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.	In stability sheets 1ml glass ampoule is written by typographic mistake, corrected stability sheets are attached
10.	2.3.R.1.1	Submit minimum handling capacity of the equipment used in the formulation of trail batches.	Firm submitted the data of Minimum handling capacity of the equipment used for trial batches

Decision of 330th meeting of Registration Board:

Deferred for the submission of following shortcomings:

- Scientific rationale for not performing terminal sterilization, with reference to the innovator product.
- Justify the quantitative composition of Sodium metabisulphite and Benzyl alcohol with reference to the innovator product, sinec the submitted reply has not verified from *USFDA Inactive ingredient database.*

Reply of the Firm:

- **Scientific rationale for not performing terminal sterilization, with reference to the innovator product.**

Firm replied that "Diflo injection 75mg/3ml was sterilized by filtration method and stability data (Accelerated and Long term stability study) submitted which gives satisfactory results of all parameters including sterility test. Further, firm commit they will terminally sterilize the commercial batched of applied product and submit undertaking accordingly.

- **Justify the quantitative composition of Sodium metabisulphite and Benzyl alcohol with reference to the innovator product, since the submitted reply has not verified from *USFDA Inactive ingredient database***

Firm replied that they developed applied product as per MHRA approved voltarol injection which only gives qualitative composition and it does not mention qualities of excipients, applied product stability study results are satisfactory of both accelerated and long term condition.

However, the PIL of voltarol injection available on MHRA website clearly mentioned that "*This medicine contains 120mg benzyl alcohol per 3ml ampoule which is equivalent to 40mg/ml. Benzyl alcohol may cause allergic reactions."*

Decision of 331st meeting of Registration Board:

Registration Board deferred the case for submission of stability studies data for three new batches, manufactured with revised formulation as per innovator drug product along with fee of registration i.e. Rs. 30,000 for submission of new stability studies data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Response of the Firm:
Firm in compliance of above decision of Registration Board submitted the stability study data of three new trial batches, manufactured with revised formulation as per innovator drug product. Stability data sheets, raw data sheets, Batch manufacturing Record, chromatograms, audit trail reports and data loggers are submitted along with requisite fee of 30,000/- deposited vide slip no. 16617669066.

Batch No.	23ARn010	23ARn011	23ARn012
Batch Size	1800 ampoules	1800 ampoules	1800 ampoules
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	14-12-2023	14-12-2023	14-12-2023
No. of Batches	03		

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

CASES OF FINISHED IMPORT RECEIVED ON FORM 5-F:

952.	**Name, address of Applicant / Importer**	**M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi.**
	Details of Drug Sale License of importer	**DSL No**.: 0230 **Address**: Al-Habib Pharmaceuticals, 81-B, block B, SMCHS, Karachi. **Godown:** 1. Plot No. 393/7 & 393/8 Sector 7-A K I A Karachi Validity: 18/05/2024 Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	**KOREA UNITED PHARM. INC.** Address: 25-23, Nojanggongdan-gil, Jeondong-myeon, Sejong-si, Korea
	Name, address of manufacturer(s)	**KOREA UNITED PHARM. INC.** Address: 25-23, Nojanggongdan-gil, Jeondong-myeon, Sejong-si, Republic of Korea
	Name of exporting country	Republic of Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized CoPP (certificate No. 2022-GI-0421) dated March 24,2022 issued by Daejeon Regional Food and Drug Administration. The applied product is available for free sale in exporting country. The facilities and operations conform to WHO-GMP.
	Details of letter of authorization / sole agency agreement	Notarized copy of sole agency agreement is submitted whereby M/s KOREA UNITED PHARM. INC authorizes M/s Al-Habib Pharmaceuticals to Import and commercialize products Leucovorin Calcium 200mg/20ml Solution for injection.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 11124 dated 09-05-2022
	Details of fee submitted	PKR 150,000 Dated: 18-04-2022
	The proposed proprietary name / brand name	**KU Nyrin (Leucovorin Calcium) 200mg injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 20ml Vial contains: **Leucovorin Calcium ……. 220mg (As Folinate 200mg)**
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Folic Acid Analogs (Adjuvant Therapy for Cancer) (V03AB)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10 Vials/Box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Leucovorin Calcium 200mg by FRESENIUS KABI USFDA**
	For generic drugs (me-too status)	Not Confirmed from the available data
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Zhejiang Davi Pharmaceutical Co., Ltd. No.818, Xinzhu Road Street Avenue, Economy Development Zone, Huzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 3°C/60 RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product **Ferbon Injection by Samjin Pharm. Co., Ltd.**
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	1. 20 mL Amber Type I Glass Vial 2. 22 mm Gray chlorobutyl rubber stoppers 3. Green aluminum/plastic flip-off caps
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches for 36 months' real time stability data at 5 ± 2 ºC; 06 month accelerated stability data 25 ± 2 ºC; HR 60 ± 5%. of 03 batches

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Provide evidence of me-too status of applied strength, since you have not submitted the requisite information.	
2.	**3.2.S.4.1**	Submit specification of drug substance by both drug substance manufacturer and drug product manufacturer.
3.	**3.2.S.4.2**	Submit detailed method of analysis of the drug substance both by drug substance manufacturer and drug product manufacturer instead of referring to USP monograph.
4.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer, as per the CTD guidance document approved by Registration Board.
5.	**3.2.S.4.4**	Justify for not including the result of water content test in the COA of drug substance , since the water content test is recommended by USP.
6.	**3.2.S.5**	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
7.	**3.2.P.1**	Justify for using preservative in the formulation of applied product, since the innovator/reference product was not using the preservative in their formulation.
8.	**3.2.P.2.2.1**	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".
9.	**3.2.P.2.2.2**	Provide scientific justification for use of 3% overage in the formulation.
10.	**3.2.P.3.3**	Provide details regarding the method of sterilization of the drug product because, during manufacturing of drug product neither you have performed terminal sterilization nor the filling has been done in aseptic conditions.
11.	**3.2.P.5.3**	You have submitted the analytical method validation report of strength 50mg/5ml Nyrin Injection instead of 200mg/20ml strength, submit the verification report of applied strength
12.	**3.2.P.5.4**	Justify for adjusting the pH of injection towards the higher value i.e. 8.1 as reflected from the submitted batch analysis report, while the reference product approved in USFDA recommends to adjust at 7.8.

13.	**2.3. R.1.1**	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.

Decision of 331st Meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification of drug substance by both drug substance manufacturer and drug product manufacturer.	Firm submitted the requisite documents.
2.	Submit detailed method of analysis of the drug substance both by drug substance manufacturer and drug product manufacturer instead of referring to USP monograph.	Firm submitted the requisite documents.
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer, as per the CTD guidance document approved by Registration Board.	Firm submitted the requisite documents.
4.	Justify for not including the result of water content test in the COA of drug substance , since the water content test is recommended by USP.	Amended COA of drug substance containing water determination test is submitted by the firm.
5.	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.	Submitted
6.	Justify for using preservative in the formulation of applied product, since the innovator/reference product was not using the preservative in their formulation.	Firm submitted the letter of justification from **KOREA UNITED PHARM. INC.**Address: 25-23, Nojanggongdan-gil, Jeondong-myeon, Sejong-si, Republic of Korea, in which the firm stated that Nyrin Injection 200mg/20ml was developed as generic products to the originator product Calcium Folinate 10mg/ml Injection manufactured by M/s. Hospira which contained preservative. The preservative in Nyrin Injection is controlled according to pharmacopeia (Between 80.0% and 120.0%). No significant changes were observed as a result of the long term and accelerated stability test.
7.	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted pharmaceutical equivalence report against the generic product Ferbon Injection of M/s. Samjin Pharma Co. Ltd.
8.	**Provide scientific justification for use of 3% overage in the formulation**. Firm replied that "The overage was added to the formulation to compensate with any loss during the manufacturing process. When it was prepared, all raw materials including active substance was 3% over-filled to compensate actual volume.	

	<table><tr><th>Manufacturing Step</th><th>Overage (%)</th><th>Justification</th></tr><tr><td>Preparation</td><td>3%</td><td>API and Excipients should be increased by 3% from the amount approved to compensate actual volume.</td></tr><tr><td>Filling</td><td>3%</td><td>The preparation solution should be increased by 3% to compensate actual volume.</td></tr></table> The Volume variation test after the filling process is performed. The PV report show the result of Volume variation after the filling process (Filling volume: 20.6 mL/V), and the result is suitable in specification (Specification: 20.30-20.90 mL/V). Since overfilling is done after over weighing (overage) for all raw materials, there is no effect to the concentration of the finished product.	
9.	Provide details regarding the method of sterilization of the drug product because, during manufacturing of drug product neither you have performed terminal sterilization nor the filling has been done in aseptic conditions.	Firm replied that with the Media Fill validation protocol that preparation process, filtration process, filling process and sealing process in the process for vial Injection is always performed within the acceptable contamination limit by simulating the aseptic process according to regular revalidation of the SVP filling workplace.
10.	You have submitted the analytical method validation report of strength 50mg/5ml Nyrin Injection instead of 200mg/20ml strength, submit the verification report of applied strength	Firm submitted the analytical method verification report of strength 200mg/20ml.
11.	Justify for adjusting the pH of injection towards the higher value i.e. 8.1 as reflected from the submitted batch analysis report, while the reference product approved in USFDA recommends to adjust at 7.8.	Firm submitted the letter of justification from **KOREA UNITED PHARM. INC.**Address: 25-23, Nojanggongdan-gil, Jeondong-myeon, Sejong-si, Republic of Korea, in which the Manufacturer Abroad stated that pH of Nyrin Injection 200mg/20ml is controlled according to Leucovorin Calcium Injection in USP is between pH :6.5-8.5.
12.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

953.	Name, address of Applicant / Marketing Authorization Holder	**Innovegic Pharmaceuticals** **Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad.**
	Detail of Drug Sale License	License No:1605 Address: Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad. Status:License to sell drug as distributor
	Name and address of Marketing authorization holder(abroad)	ADOH B.V Godfried Bomansstraat 31 6543 JA Nijmegen,The Netherland
	Name, address of Manufacturer	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, 571127, China

	Status of the applicant	☐ Manufacturer ☑ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting Country	China
	Detail of certificate attached (COPP, Free sale certificate, GMP certificate)	Firm has submitted COPP Certificate No:21-00428 valid up to 11-03-2024 issued by Ministry of Health, Welfare and sport, Netherland and according to which product License holder is ADOH B.V Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. GMP certificate of Hainan poly pharma was granted by Republic of China valid upto29-01-2024.
	Detail of letter of authorization/sole agency agreement	Submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☑Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10232 dated 21-04-2022
	Details of fee submitted	PKR 150,000/-: dated 14-01-2022
	The proposed proprietary name / brand name	Telisin injection 8.5ml:0.85mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 1mg of terlipressin acetate equivalent to 0.85mg of terlipressin
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Posterior Pituitary Lobe hormone(Vasopressin and analogues)
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	5x8.5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glycopressin injection by Ferring Pharmaceuticals, UK.
	For generic drugs (me-too status)	Europress Injection by M/s Rotex Medica Pharmaceuticals ,Islamabad
	Name and address of API manufacturer.	Chinese Peptide Company No.69,12th Street,HEDA Zhejiang,310018 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies of Drug Substance	Stability study conditions: Real time: 2-8°C for 18 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months Batches: (18082701, 18090601, 18120702)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies of Drug Product	Stability study conditions: Real time: 2-8°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months Batches: (T190707, T190708, T190709)
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence performed against RMP Glycylpressin of M/s. Ferring Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.3	• Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate. • Further, submit letter of authorization/sole agent agreement from Product license holder i.e. M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.
2.	3.2.S.4.1	Justify for not adopting the BP specification for the analysis of drug substance when the monograph of drug substance is available in BP.
3.	3.2.S.4.2	Please clarify the analytical method used for analysis of amino acid, since the submitted procedures of amino acid analysis are not in accordance with the reference general chapter of amino acid i.e.2.2.56 as mentioned in BP monograph of terlipressin.
4.	3.2.S.4.4	Please submit the English translated copy of COA of drug substance by drug substance manufacturer.
5.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
6.	3.2.P.1	Scientific justification is required for using overage of active ingredient in the formulation along with overfilling of quantity per vial.
7.	3.2.P.2.2 .1	Provide pharmaceutical equivalence report in which comparative quality analysis of both tested product and reference product should be presented in the tabulated form.
8.	2.3.R.1. 1	Please clarify the fill volume range mentioned in BMR i.e. between 9.12g-9.30g with reference to the label claim of applied product which is 0.85mg Terlipressin (base free) contains in 8.5ml solution.

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Sections	Short-comings	Response of the Firm
1.	1.3.3	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate.	Firm submit the original legalized CoPP (certificate no. 20230131) issue dated 25-10-2023 by Hainan Provincial Medical Products Administration and valid till 24-10-2025.
2.	1.3.3	Further, submit letter of authorization/sole agent agreement from Product license holder i.e. M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.	Firm not submitted the reply of this query.
3.	3.2.S.4.1	Justify for not adopting the BP specification for the analysis of drug substance when the monograph of drug substance is available in BP.	Firm replied that the proposed specification of drug substance is equivalent or stricter than BP monograph of Terlipressin.
4.	3.2.S.4.2	Please clarify the analytical method used for analysis of amino acid, since the submitted procedures of amino acid analysis are not in accordance with the reference general chapter of amino acid i.e.2.2.56 as mentioned in BP monograph of terlipressin.	Firm replied that the specification and analytical procedure of analysis of amino acid is established as per the specification and analytical procedure listed in CEP of terlipressin, which has been approved by EMA. Since the analytical procedure listed in Ph. Eur. 2.2.56 are the general procedure which are not established for the specific product, so the proposed analytical procedure is not exactly same as the method in Ph. Eur. 2.2.56. The proposed method is specific for the Terlipressin manufactured by Chinese Peptide Company and also the proposed analytical procedure has been fully validated for the use.
5.	3.2.S.4.4	Please submit the English translated copy of COA of drug substance by drug substance manufacturer.	Submitted
6.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.	Submitted

7.	3.2.P.1	Scientific justification is required for using overage of active ingredient in the formulation along with overfilling of quantity per vial. Firm replied that there is no overage in the proposed drug product. The filling weight is determined on analysis on RMP and extractable study. Firstly, the analysis on RMP shows that the filling volume of RMP is about 9ml, so we firstly designed a filling volume of 9ml equivalent to 9.03g, to achieve the quantitative equivalence with the RMP. Secondly, according to USP <1151>, each container of an injection is filled with a volume in slight excess of the labelled size, a series of extractable quantity studies were performed. The study result demonstrated that when control the filling weight above 9.03g (i.e.9ml) the actual available extractable amount can satisfy the labelled amount (8.5ml, equal to 8.53g). The concentration of terlipressin in terlipressin solution for injection is 0.1mg/ml, thus the quantity of terlipressin in each vial should be 0.9mg (calculated on anhydrous, acetic acid free-base). Compared to label amount of 0.85mg, there is about 6% overfill. However, the manufacturer should follow the general guidance of USP <1151> on the target volume i.e. 8.5 ml as per the label claim of drug product instead of targeting the filled volume of reference pack of RMP.	
8.	3.2.P.2.2.1	Provide pharmaceutical equivalence report in which comparative quality analysis of both tested product and reference product should be presented in the tabulated form.	Firm submitted the pharmaceutical equivalence report performed against the product GLYCYLPRESSIN (batch no. N00043C).
9.	2.3.R.1.1	Please clarify the fill volume range mentioned in BMR i.e. between 9.12g-9.30g with reference to the label claim of applied product which is 0.85mg Terlipressin (base free) contains in 8.5ml solution.	Firm replied that in order to achieve the quantitative equivalence with the RMP and ensure the sufficient extractable quantity (i.e. 0.85mg terlipressin) of terlipressin solution for injection, the minimum filling weight is determined to be 9.03g I.e. the lower limit of action level is 9.03g.

Decision of 333rd meeting of Registration Board:

Deferred for following:

- Clarification is required regarding the product license holder, since the earlier submitted documents revealed that the Product license holder is M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland and the recently submitted CoPP specified that the product license holder is Hainan poly pharma Co. Ltd., China.
- Submit letter of authorization/sole agent agreement from Product license holder. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.
- Justify the target fill volume for applied product with reference to the label claim and allowable "Excess Volume in injections" as per USP General Chapter <1151>.

Response of the Firm:

- **Clarification is required regarding the product license holder, since the earlier submitted documents revealed that the Product license holder is M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland and the recently submitted CoPP specified that the product license holder is Hainan poly pharma Co. Ltd., China.**

Firm replied that the product License holder is M/s. Hainan Poly Pharma Co. Ltd., China. After completing the manufacturing of submission batches for Terlipressin solution for injection, we applied for registrations in several markets, including the Netherlands and China. At the time of the initial submission in Pakistan, only the Netherlands market was approved, so the CoPP they submitted was applied from the Netherlands. According to the rules governing medicinal products in the European Union, volume 2A.

The marketing Authorization holder must be established within EEA. &quot: so in the CoPP that they applied from the Netherlands, ADOH (established within the EEA) is embodied as the MAH, and the Hainan Poly is embodied as the Manufacturer. Therefore, the earlier submitted documents revealed that the Product license holder is M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen.

Then, at the time of providing the recent CoPP, Terlipressin solution for injection was already approved in China, so we applied the CoPP IN China in order to reply to the Pakistan Agency as early as possible. The

recent CoPP was based on the product approved in China, so Hainan Poly was reflected as the MAH in the CoPP.

- **Submit letter of authorization/sole agent agreement from Product license holder. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.**

Firm submitted copy of sole agent Authorization letter in which it is specify that M/s. Hainan Poly Pharm. Co. Ltd., Guilinyang Economic Development Area, Haikou, Hainan Province, 571127, China have duly authorized M/s. Innovegic Pharmaceuticals to act as the agent for the registration, sale, and marketing of product Terlipressin Injection in Pakistan.

- **Justify the target fill volume for applied product with reference to the label claim and allowable "Excess Volume in injections" as per USP General Chapter <1151>.**

Firm replied that the fill volume of applied product is 9ml(i.e.9.03g), also conform to the requirement as listed in USP General Chapter <1151>.

Recommended Excess Volume		
Labeled Size	**For Mobile Liquids**	**For Viscous Liquids**
0.5 mL	0.10 mL	0.12 mL
1.0 mL	0.10 mL	0.15 mL
2.0 mL	0.15 mL	0.25 mL
5.0 mL	0.30 mL	0.50 mL
10.0 mL	0.50 mL	0.70 mL
20.0 mL	0.60 mL	0.90 mL
30.0 mL	0.80 mL	1.20 mL
50.0 mL or more	2%	3%

Labelled size of the applied product is 8.5ml based on the information given in the above table 0.5ml of the excess volume should be proposed, therefore the fill volume 9ml of the applied product conform to the requirement of USP General Chapter <1151> (8.5ml +0.5ml=9ml).

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

954.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address:793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06. Feb.2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3304 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.16108 , Date: 10.06.2021
	Details of fee submitted	PKR.100,030/- Date: 29-01-2021
	The proposed proprietary name / brand name	Sunitix 25mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN …….25mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 25mg capsule USFDA approved
	For generic drugs (me-too status)	Sutent (Pfizer Laboratories) Reg.no. 052226
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Sutent 25mg capsule (Pfizer Laboratories) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 28 capsules)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Sr. no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studies GC method for determination of residual solvent of Sunitinib Malate.	Firm has submitted the reply of this query.
2.	Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of	Firm has not submitted the reply of this query.

	active material and excipient are filled in capsules.	
3.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm has not submitted the reply of this query.
4.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.Justification is required regarding the disparity in acceptance criteria of assay of drug product.	Firm has not submitted the reply of this query.
5.	As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.	Firm has not submitted the reply of this query.
6.	According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be *"Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C"*. While the dissolution condition specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document. Scientific justification is required in this regard.	Firm has not submitted the reply of this query.
7.	Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "*for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*	Firm has not submitted the reply of this query.

8.	Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.	Firm has not submitted the reply of this query.
9.	• Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value. • Analytical method validation protocol specified assay method for capsule containing granules while the manufacturing process of drug product evident that capsule containing dry powder mixture of active material and excipient has been prepared. Justification is required that how the validation studies performed on assay method of capsule containing granules be applied on capsule containing dry powder mixture of active and excipients.	Firm has submitted the revised analytical method validation for drug product.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm submitted BMR, according to which 269.19 gm of sunitinib Malate having potency of 99.3% has been for manufacturing of 8,000 capsule.
11.	Firm has already had registration of sunitinib Malate Capsule imported from Germany and details are as follows: Product License Holder: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. Manufacturer: M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta. Sunitinib Aqvida 12.5mg hard capsule (Reg.no.103778) Sunitinib Aqvida 25mg hard capsule (Reg.no.103779) Sunitinib Aqvida 50mg hard capsule (Reg.no.103780)	

Decision of 322nd meeting of Registration Board:

Deferred for submission of following:

- *Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.*
- *Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.*
- *Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.*
- *Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.*
- *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*
- *Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.*

Response of the Firm:
Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.

Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.
We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsule contains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib.
An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.

Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.

Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.

Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.

Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.

As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.

Firm replied that "We have four (04) strength of Sunitinib Capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopoeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions. So there have some variations in previous condition with current condition. In future it will be inline."
Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.

Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".

Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA, but the revised dissolution conditions and acceptance criteria is still not in accordance with innovator product.

Dissolution condition of applied product	Dissolution condition of Innovator's Formulation
Apparatus USP II (Paddle System) Dissolution medium: 0.1N HCl Volume: 500ml RPM: 50 Temperature: 37°C ± 0.5°C Dissolution Time: 60 minutes Acceptance Criteria: NLT 70% of the labeled amount of sunitinib is dissolved in 60 minutes.	Apparatus USP II (Paddle System) Dissolution medium: 0.1M HCl Volume: 900ml Temperature: 37°C ± 0.5°C Dissolution acceptance criteria : NLT Q in 30 minutes.

Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.

Firm replied that This is referring to Bioequivalence study completed for product with higher strength, bio waiver for bioequivalence is acceptable for lower strength based on bioequivalence study on higher strength, dissolution testing of both higher and lower strength and proportional similarity of the formulations between lower strength and higher strength.

Decision of 329th meeting of Registration Board:

Deferred for the submission of following shortcomings:

- Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.
- Submit separate comparative dissolution profile data of both strength of sunitix 25mg and 12.5mg capsules

Response of the Firm:

Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.

Firm submitted the dissolution conditions along with acceptance criteria in-line with innovator product. Further, submitted the validation report of dissolution method. Further, submmittd the commitment letter on the letter head of M/s Beacon Pharmaceuticals Limited, in which it is stated that "We have four strengths of sunitinib capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions in line to innovator product.

Submit separate comparative dissolution profile data of both strengths of sunitix 25mg and 12.5mg capsules

Firm submitted the CDP REPORT of sunitix capsule 25mg performed against sutent 25mg capsule of Pfizer Pharma.

Decision of 331st meeting of Registration Board:

Deferred for submission of performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Response of the Firm:

Firm submitted performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

955.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address:793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06. Feb.2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toyenbee Circular Road, Motijheel

		Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3303 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No. 16109 :Date10.06.2021
	Details of fee submitted	PKR.100,030/- Date: 29-01-2021
	The proposed proprietary name / brand name	Sunitix 12.5mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN…….12.5mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 12.5mg capsule USFDA approved

	For generic drugs (me-too status)	Sutent capsule 12.5mg (Pfizer Laboratories) Reg.no.052225
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Sutent 12.5mg capsule (Pfizer Laboratories) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 28 capsules)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Sr. no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studies GC method for determination of residual solvent of Sunitinib Malate.	Firm has submitted the reply of this query.

2.	Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient are filled in capsules.	Firm has not submitted the reply of this query.
3.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm has not submitted the reply of this query.
4.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.Justification is required regarding the disparity in acceptance criteria of assay of drug product.	Firm has not submitted the reply of this query.
5.	As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.	Firm has not submitted the reply of this query.
6.	According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be *"Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C"*. While the dissolution condition specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document. Scientific justification is required in this regard.	Firm has not submitted the reply of this query.
7.	Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "*for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*	Firm has not submitted the reply of this query.
8.	Same comparative dissolution profile data has been submitted for sunitix 25 capsule and	Firm has not submitted the reply of this query.

	sunitix 12.5 capsule, clarification is required in this regard.	
9.	Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value. Analytical method validation protocol specified assay method for capsule containing granules while the manufacturing process of drug product evident that capsule containing dry powder mixture of active material and excipient has been prepared. Justification is required that how the validation studies performed on assay method of capsule containing granules be applied on capsule containing dry powder mixture of active and excipients.	Firm has submitted the revised analytical method validation for drug product.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm submitted BMR, according to which 269.19 gm of sunitinib Malate having potency of 99.3% has been for manufacturing of 8,000 capsule.
11.	Firm has already had registration of sunitinib Malate Capsule imported from Germany and details are as follows: Product License Holder: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. Manufacturer: M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta. Sunitinib Aqvida 12.5mg hard capsule (Reg.no.103778) Sunitinib Aqvida 25mg hard capsule (Reg.no.103779) Sunitinib Aqvida 50mg hard capsule (Reg.no.103780)	

Decision of 322nd meeting of Registration Board:
Deferred for submission of following:

- *Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.*
- *Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.*
- *Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.*
- *Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.*
- *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*
- *Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.*

Response of the Firm:
Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.

Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.
We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsule contains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib.
An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.

Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.

Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.

Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.

Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.

As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.

Firm replied that "We have four (04) strength of Sunitinib Capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopoeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions. So there have some variations in previous condition with current condition. In future it will be inline."
Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.

Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".

Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA, but the revised dissolution conditions and acceptance criteria is still not in accordance with innovator product.

Dissolution condition of applied product	Dissolution condition of Innovator's Formulation
Apparatus USP II (Paddle System) Dissolution medium: 0.1N HCl	Apparatus USP II (Paddle System) Dissolution medium: 0.1M HCl

Volume: 500ml RPM: 50 Temperature: 37°C ± 0.5°C Dissolution Time: 60 minutes Acceptance Criteria: NLT 70% of the labeled amount of sunitinib is dissolved in 60 minutes.	Volume: 900ml Temperature: 37°C ± 0.5°C Dissolution acceptance criteria : NLT Q in 30 minutes.

Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.

Firm replied that This is referring to Bioequivalence study completed for product with higher strength, bio waiver for bioequivalence is acceptable for lower strength based on bioequivalence study on higher strength, dissolution testing of both higher and lower strength and proportional similarity of the formulations between lower strength and higher strength.

Decision of 329th meeting of Registration Board:

Deferred for the submission of following shortcomings:

- Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.
- Submit separate comparative dissolution profile data of both strength of sunitix 25mg and 12.5mg capsules

Response of the Firm:

Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.

Firm submitted the dissolution conditions along with acceptance criteria in-line with innovator product. Further, submitted the validation report of dissolution method. Further, submmittd the commitment letter on the letter head of M/s Beacon Pharmaceuticals Limited, in which it is stated that "We have four strengths of sunitinib capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions in line to innovator product.

Submit separate comparative dissolution profile data of both strengths of sunitix 25mg and 12.5mg capsules

Firm submitted the CDP REPORT of sunitix capsule 12.5mg performed against sutent 12.5mg capsule of Pfizer Pharma.

Decision of 331st meeting of Registration Board:

Deferred for submission of performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Response of the Firm:

Firm submitted performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

956.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block 'C', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address:793-D,Block-C,Faisal Town Lahore Address of Godown: NA Validity: 06.Feb.2024 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh

	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3305 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/5027).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.32074 dated 23-11-2021
	Details of fee submitted	PKR 100,000/- 01-02-2021 PKR 50,000/- 12.07.2021
	The proposed proprietary name / brand name	Sunitix 50mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN …….66.825mg eqv to Sunitinib 50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 50mg capsule

	For generic drugs (me-too status)	Sutent (Pfizer Laboratories)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Sutent 50mg capsule (Pfizer Laboratories) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 28 capsules)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 36 months
Evaluation by PEC:		

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid certificate of Good Manufacturing Practices of drug product manufacturer, since the submitted document has been expired in 2021.	Firm submitted the GMP certificate no. DA/6-110/06/6751 dated 23rd March,2023 issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid for 2 years.
2.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studies GC method for determination of residual solvent of Sunitinib Malate.	Firm submitted the analytical verification data of drug substance.
3.	Scientific justification is required that how your applied product be equivalent to innovator product as the sutent brand is the capsule filled with granules, while the applied product is the capsule filled with dry powder mixture of active material and excipient.	Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards. We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsule contains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib. An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.
4.	*According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be "Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C". While the dissolution medium specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document in term of use of surfactant. Scientific justification is required for using different dissolution medium from that of innovator product approved in USFDA.* *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes in light of FDA dissolution database and innovator product's review literature. Since the acceptance criteria as per the FDA dissolution database refer to FDA's dissolution guidance 2018 in which it is recommended that "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes", further, the innovator product approved in FDA also recommend Q at 30 minutes.* Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA along with revised CDP report.	

	Dissolution condition of applied product	Dissolution condition of Innovator's Formulation
	Apparatus USP II (Paddle System) Dissolution medium: 0.1N HCl Volume: 900ml RPM: 50 Temperature: 37°C ± 0.5°C Dissolution Time: 30 minutes Acceptance Criteria: NLT 80% of the labeled amount of sunitinib is dissolved in 30 minutes.	Apparatus USP II (Paddle System) Dissolution medium: 0.1M HCl Volume: 900ml Temperature: 37°C ± 0.5°C Dissolution acceptance criteria : NLT Q in 30 minutes.
5.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.
6.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt form or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule i.e.45.0mg to 55.0m. Justification is required regarding the disparity in acceptance criteria of assay of drug product in various sections.	Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.
7.	Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value.	Firm has submitted the revised analytical method validation for drug product.
8.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted

Decision of 333rd meeting of Registration Board:
Deferred for submission of performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Response of the Firm:
Firm submitted performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

957.	Name, address of Applicant / Importer	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi Address of Godown: Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi Validity: 04-08-2024 Status: Valid
	Name and address of marketing authorization holder (abroad)	M/s. Jiangsu Hengrui Medicine Co. Ltd. 7 Kunlunshan Road, Economic and Technological Development Zone Lianyungang Jiangsu 222047 China

	Name, address of manufacturer(s)	M/s. Jiangsu Hengrui Medicine Co. Ltd. Dongjin Road, Port Industry Area, Economic and Technological Development Zone, Lianyungang, Jiangsu, China
	Name of exporting country	United States of America(as per the submitted copy of CoPP)
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted a commitment letter "that they shall submit the original embassy legalized valid Certificate of Pharmaceutical Product (CoPP) of applied product Iodopaque Injection 320mgI/ml-100ml vial within 3 months. GMP Certificate: Firm has submitted GMP Certificate No. Su20160311 issued by Jiangsu Drug Administration. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Distribution Certificate from M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd., No. 38, Huanghe Road, Economic& Technological Development Zone, Lianyungang. The letter specifies that the manufacturer authorize M/s. Lab Diagnostics System (SMC) Pvt. Ltd. to sell and participate on behalf of Jiangsu Hengrui Pharmaceuticals Co. Ltd. in government, semi government and other local tender and sign sale contracts pertaining to the aforesaid tenders and also allowed to distribute our products (brand name: IODOPAQUE Injection 320mg I/ml (100 ml & 200ml) in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 27225 dated 17th November,2023
	Details of fee submitted	PKR 150,000/- vide slip no. 93315011 dated: 25-10-2023
	The proposed proprietary name / brand name	Iodopaque Injection 320mgI/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	320mg Iodine/ml (100ml vial)
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Iodinated Contrasting Media
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA (Iodixanol 350mgI/ml,100ml)
	For generic drugs (me-too status)	Visipaque 320mgI/ml (50ml as per available data)(Reg.no.043052) M/s. Bayer
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. (Jinqiao Road Site) 22 Jinqiao Road, Dapu Industrial Park, Economic and Technological Development Zone, Lianyungang, Jiangsu 222002, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated and real time stability data are conducted at (40±2ºC/75±5%RH) and (25±2ºC/60±5%RH) respectively. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the reference listed drug Visipaque 320 NDA 020351 of M/s. GE Healthcare.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Iodixanol Injection 320mgI/ml is filled into 100ml colourless and translucent polypropylene bottle, sealed with a grey bromobutyl rubber stopper and secured with a colorless polypropylene cap (PP cap) with tamper-evident ring.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of batches of volume sizes 50ml,100ml & 150ml. The accelerated stability study data is conducted at 40ºC ±2ºC / 20% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC /35 % ± 5% RH.

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.3	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin. Further, clarification is required either the drug product is import from China or United States of America, since you have submitted the copy of CoPP/ Free sale certificate in which the exporting country is United State of America, while the Manufacturer, manufacturing authorization holder and letter of authorization is M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. China .

Decision of 333rd meeting of Registration Board:
Deferred for submission of valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin. Further, clarification is required either the drug product is imported from China or United States of America, since you have submitted the copy of CoPP/ Free sale certificate in which the exporting country is United State of America, while the Manufacturer, manufacturing authorization holder and letter of authorization is from M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. China .

Response of the Firm:
Firm submitted the copy of CoPP certificate no. 20230505 validity 30-08-2025 and the CoPP was verified from the website of national medical product database of China.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

958.	**Name, address of Applicant / Importer**	M/s. Revive Health Care, Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan.
	Details of Drug Sale License of importer	License No: **05-352-0065-031159D** Address: Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan. Address of Go down: NA Validity: **21.05.2027** Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name, address of manufacturer(s)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-134/09/10160 issued on 21-05-2023 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DGDA/6-134/09/195) issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid upto 30-09-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from M/s. Jenphar Bangladesh Limited. The letter specifies that the manufacturer appoints M/s Revive Health Care. to register their products in

		Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.24504 , Date: 06-10-2023
	Details of fee submitted	PKR 75,000/- 19/09/2023
	The proposed proprietary name / brand name	Tasso Tablet 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Osimertinib (as mesylate)…..80mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors (L01EB04)
	Reference to Finished product specifications	In house
	Proposed Pack size	As per SRO
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Tagrisso 80mg Tablet (USFDA Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	ShengDa Pharmaceutical Co., Limited.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 3 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 3 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Tagrisso 80mg Tablet (M/s. AstraZeneca) has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Therapeutic indications TAGRISSO as monotherapy is indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product.
2.	1.3.5	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug*" Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.
3.	3.2.S.2.1	Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer.
4.	3.2.S.4.1-3.2.S.4.2	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.
5.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
6.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
7.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.
8.	3.2.S.7	Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month.

9.	3.2.P.2.6	Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development.
10.	Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address.	
11.	3.2.P.5.1	Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes.
12.	3.2.P.5.4	Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.
13.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.

Decision of 333rd meeting of Registration Board:
Deferred for submission of reply to above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product.	Firm submitted the product specific Letter of authorization from the product License Holder.
2.	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug*" Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.	Firm submitted a letter mentioning that they have separate oncology manufacturing facility without any GMP certificate or inspection report.
3.	Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer.	Firm submitted the complete address of API manufacturer "M/s. Shengda Pharmaceuticals Co. Ltd., Block H, Zhigu Industrial Park, Yintian Road, Xixiang, Baoan, Shenzhen China".
4.	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
5.	Provide analytical method validation report performed by drug product manufacturer.	Submitted
6.	Provide batch analysis report of drug substance by the drug product manufacturer.	Submitted

7.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted
8.	Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month.	Firm submitted the stability data of drug substance till the re-test period of 24 months.
9.	Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development.	Firm submitted SmPC of the applied product in which the tablet aqueous dispersion preparation has been given. Further submit the tablet dispersion comparative study of applied product.
10.	**Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis- Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address.** Firm replied that Manufacturer of the product is M/s. Jenphar Bangladesh Limited **(Vill-Faridpur, PS-Sreepur Dis- Gazipur)** a changed name from M/s. Julphar Bangladesh Ltd. With same address. Further applicant replied that Manufacturer has performed CDP of the applied product with innovator as well as local Me-Too available products in Bangladesh, if the conclusion of CDP report of other company is mistakenly attached then please ignore it.	
11.	Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes.	Firm replied that in submitted CDP the dissolution profile showed the dissolution results greater than 93% of all three medias after 30 minutes which meets the acceptance criteria NLT 80%(Q), where manufacturer of the product decided the time of dissolution 45minutes where results are greater than 100%. However, according to general chapter of USP <1092> "*During product development, the collection of complete dissolution profile data is recommended from biobatches and stability batches at specified intervals, such as 10, 15, 20, 30, 40, 50, and 60 min or 15, 20, 30, 45, and 60 min, because these data are used to establish the dissolution acceptance criterion/criteria. From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%. However, this time point should not be less than 15 min".*
12.	Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s.	Firm submitted change of company name letter from Julphar to Jenphar in the reply of this query.

	Jenphar Bangladesh Ltd., clarification is required in this regard.	

Decision: Deferred for submission/clarification of following:

- **Justify for adopting the dissolution acceptance limit NLT 80% (Q) within 45 minutes for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes, when the dissolution profile showed the dissolution results greater than 85% of all three medias within 30 minutes. Since USP general chapter <1092> recommends that "*From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%".***
- **Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.**

959.	Name, address of Applicant / Importer	M/s. VIZ Remedies Pakistan LLP
	Details of Drug Sale License of importer	License No. 1174 Address: Suit No.26 4th Floor Kehkashan Mall, Tariq Road. Block-2 PECHS Karachi Address of Go down: NA Validity: 13-02-2022 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name, address of manufacturer(s)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted copy of CoPP certificate (No: 20200029) dated 16-06-2020 issued by Shaanxi Provincial Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned. Furthermore, the CoPP was valid till 15-06-2022. Copy of GMP certificate of M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. is submitted which was valid till 22-09-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Exclusive Marketing Agreement between M/s. VIZ Remedies Pakistan LLP and M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. The letter specifies that the manufacturer appoints M/s. VIZ Remedies Pakistan LLP. Is their exclusive agent in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24063 : dated 01-09-2021
	Details of fee submitted	PKR 100,000/-: dated 18-01-2021 (Differential fee of Rs. 50,000/- is to be submitted by the firm)
	The proposed proprietary name / brand name	Tirofiban Hydrochloride Injection 5mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL contains: Tirofiban Hydrochloride (calculated based on Tirofiban)5mg
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Anti-Platelet
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x100ml neutral borosilicate glass infusion bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (AGGRASTAT Injection)
	For generic drugs (me-too status)	Not confirmed in the applied volume i.e.100ml
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of Tirofiban hydrochloride Injection instead of Tirofiban hydrochloride API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence study has been performed against the innovator product AGGRASTAT Injection (Batch no. C856260) which includes quality test (Appearance, pH , Assay, Citric Acid and sodium citrate content, sodium chloride content and related substance test.)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml- neutral borosilicate glass Infusion bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 following batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. B171001,B171002,B171003

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
2.	1.4	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.
3.	3.2.S.7	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.
4.	3.2.P.3	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.
5.	3.2.P.5.1	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.
6.	3.2.P.5.4	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.

Decision of 326th meeting of Registration Board:

Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.	Firm replied that they submitted original and legalized CoPP at the time of registration. However due to its expiration, renewed CoPP has been requested to the principal manufacturer.
2.	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.	Firm submitted the copy of DSL no. 0324 which is valid till 14/03/2028.

3.	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.	Firm submitted the stability data of 36 months of three batches performed at long term conditions.
4.	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.	Firm in their reply submitted a document, which only stated the quality parameters used for the analysis of activated charcoals INSTEAD of providing reference from international standard to rationalize the use of activated charcoal for sterilizing the injectable solution..
5.	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.	Firm clarify that they quantify the quantity of tirofiban by using external standard method, the obtained assay is for tirofiban hydrochloride, then the results will multiply by conversion coefficient (0.8899) to obtain labelled amount of Tirofiban.
6.	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.	Firm replied that the role of sodium chloride in this formulation is as "Osmotic Pressure Modifier".

Decision of 333rd meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
- Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.

Response of the Firm:

- **Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.**

Firm replied that the valid original and legalized Certificate of Pharmaceutical Product (CoPP) were submitted at the time of submission of registration application.

- **Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.**

Firm submitted guidance document of PMDA, Japan "Guidance on the Manufacture of Sterile Pharmaceutical Products by Aseptic Processing" but the submitted documents did not contain any material relevant to the use of activated charcoal carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin. Further, firm submitted the patent documents of tirofiban hydrochloride as a proof of use of activated carbon instead of tirofiban hydrochloride injection.

Decision:Deferred for submission of relevant guidance document of reference agencies which clearly recommends the usage of activated carbon in the manufacturing procedure of sterile preparation for removal of bacterial endotoxin.

960.	**Name, address of Applicant / Importer**	**M/s Al Habib Pharmaceuticals**
	Details of Drug Sale License of importer	**License No:** 0230 **Address:** 81-B Block B, S.M.C.H.S., Karachi **Address of Godown:** 393/7,393/8 Sector 7-A KIA Karachi **Validity:** 19/05/2022 till 18/05/2024 **Status:** License to sell drugs as distributor **Renewal:** Valid
	Name and address of marketing	Naprod Life Sciences Pvt. Ltd.

	authorization holder (abroad)	Plot no. G-17/1,MIDC,Tarapur,Boisar,Thane 401506 Maharashtra State, India
	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd. Plot no. G-17/1,MIDC,Tarapur,Boisar,Thane 401506 Maharashtra State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COPP/CERT/KD/104901/2021/11/1799901) dated 16 August, 2021 (valid till 03-April,2022) issued by Food & Drug Administration Maharashtra State, Mumbai for Macabi (Bicalutamide Tablets USP 50mg). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. Certificate of renewal of Licence to Manufacture of M/s. NAPROD LIFE SCIENCES PVT. LTD valid from 01-01-2017 to 31-12-2021. Certificate of Good Manufacturing Practices of M/s. Naprod Life Sciences Pvt. Ltd. Maharashtra State, India certificate no. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 DATED 04-April,2019 valid till 03-April,2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Authorization from M/s. Naprod Life Sciences Pvt. Ltd. authorize to M/s. Al Habib Pharmaceuticals, Karachi as a sole agent and distributor of Macabi (Bicalutamide) Tablet 50mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5227 dated 24-02-2022
	Details of fee submitted	PKR 150,000/-: dated 26-01-2022
	The proposed proprietary name / brand name	**MACABI Tablets 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Bicalutamide……50mg ATC Code L02BB03
	Pharmaceutical form of applied drug	1 × 10's in Alu-Alu Blister
	Pharmacotherapeutic Group of (API)	ATC Code L02BB03 (Anti Androgens)
	Reference to Finished product specifications	USP

	Proposed Pack size	As per policy
	Proposed unit price	As per policy
	The status in reference regulatory authorities	USFDA (Casodex 50mg Tablet)
	For generic drugs (me-too status)	Casodex 50mg Tablet of M/s. ICI Pakistan Ltd., Hattar (Reg.no. 027380)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Mac Chem Products (India) Pvt. Ltd. N-211/2/10.Tarapur MIDC,Biosar,District Thane, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30ºC ± 2ºC,60%±5% RH (60 months) and accelerated time stability study conducted at 40°C±2°C,75%±5% RH (6 months) of following batches: BCL0211001,BCL0211002,BCL0211003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has established against the innovator product casodex 50mg Tablet (M/s. AstraZeneca Pvt. Ltd.) Batch no. 60022647. Comparative dissolution has performed in all three recommended physiological medium against the innovator brand.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu foil & PVC film coated with PVDC Blister foil.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of 10,000 tablets batch size. The accelerated stability

		study is conducted at 40°C/75%RH and data of 6 months has submitted. The real time stability study is conducted at 30°C±2°C/75%±5%RH. The real time stability study data of 24 months has been submitted. Batch no. NT1160,NT1161,NT1162

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Drug substance Bicalutamide is a racemate mixture, please provide the detail along with quantitative results, that which enantiomeric form of API has been used in the manufacturing of drug product.	Bicalutamide is racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.as single enantiomeric form is not used, enantiomeric purity is not applicable. *CASODEX is a racemate with its antiandrogenic activity being almost exclusively exhibited by the R-enantiomer of bicalutamide; the S-enantiomer is essentially inactive.*
2.	Justify for keeping the water content limit NMT 7.0% comparing the water content of active ingredient NMT 0.2%.	Firm replied that our product complies with the current USP monograph of bicalutamide tablet 50mg ,drug product monograph in USP does not contain water content test ,hence the limit of water content was given in-house based on the water content of API ,excipients and manufacturing process.
3.	justify, for submitting the validation report of 150mg strength instead of applied 50mg strength.	Submitted

Registration Board was apprised regarding an e. mail received to Director PE&R Division from M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Decision of 324th meeting of Registration Board:

Deferred for following:

- Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.
- Scientific justification regarding declaration of Bicalutamide as racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.

Response of the Firm:

- **Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.**

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, as a sole agent and distribution of following drugs only. Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.

We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
15.	Capecitabine 500mg TAB	NAPROCAP -500
16.	Methotrexate 2.5mg TAB	ALLTREX
17.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
18.	Leucovorin Calcium inj. 300mg	CAFONATE
19.	Fluorouracil inj. 500mg	FLUONCO

20.	Bicalutamide 50mg TAB	MACABI
21.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

- **Scientific justification regarding declaration of Bicalutamide as racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.**

Firm replied that drug substance is a racemic mixture of S-enantioner and R-enantiomer in a ratio of 50:50, as the review literature of innovator product also claimed that the drug substance is racemic mixture of both enantiomers.

Decision: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email.

961.	**Name, address of Applicant / Importer**	**M/s: Sohail Corporation** **Address:** Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan.
	Details of Drug Sale License of importer	**License No:** 239 **Address:** Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan. **Address of Godown:** NA **Validity:** 18-Nov-2027 **Status:** Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale **Renewal:** Our license has been renewed and the details written above are for the renewed licenses.
	Name and address of marketing authorization holder (abroad)	**M/s: Hebei Med Site medicines Co Ltd.** **Address**: No.500 Taihua Street, Xinhua District, Shijiazhuang China.
	Name, address of manufacturer(s)	**Name of Manufacturer**: Shandong Xier Kangtai Pharmaceutical Co., Ltd. **Address:** Private Economy Garden, Xinyan Town, Yanzhou District, Jining City.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized FSC certificate No: Y-F2002066 Dated 09-09-2020 issued by Jining Yanzhou Market Supervision and Administration for Doxycycline Capsules 250mg. The FSC confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. Also, firm has submitted GMP certificate no. YZ-G202003008 valid till 01-03-2025.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of Sole Agency Agreement from Shandong Xier Kangtai Pharmaceutical Co., Ltd The letter species that the manufacturer appoints M/s Sohail Corporation to register their products in Pakistan. This agreement is valid till 07-06-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 12290 dated 20-05-2022
	Details of fee submitted	PKR 100,000/-: 06-04-2021 Deposit Slip No.2073006 PKR 50,000/- Deposit Slip No: 3515278800
	The proposed proprietary name / brand name	**Doxycycline Capsules 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains 100mg doxycycline base as doxycycline hyclate.
	Pharmaceutical form of applied drug	Capsules
	Pharmacotherapeutic Group of (API)	API: Doxycycline Therapeutic classification: Tetracycline Antibiotics. ATC code: A01AB22
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	10 capsules per blister, 10 blisters per box, 200 boxes per carton.
	Proposed unit price	Rs.1200 per 10 blister box
	The status in reference regulatory authorities	**(MHRA** Approved).
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name of the manufacturer(s): Hebei Dongfeng Pharmaceutical Co., Ltd. Address of API manufacture: No.365, Guan yuan West Street, Yongnian District, Handan City, Hebei Province, Chin
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time

	studies)	stability data is conducted at 30ºC ± 2ºC and 65%+5 RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report and the test report Doxycycline Capsules 100mg are highly consistent and meet statutory standards (BP).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Doxycycline Hyclate is packed in inner clear and outer black LDPE bag individually tied with plastic seal strip then packed in fibre/HMHDPE drum and sealed with locking seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

Sr.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.3**	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate.
2.	**3.2.S.4.1-3.2.S.4.2**	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.
3.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
4.	**3.2.S.5**	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
5.	**3.2.P.2.2.1**	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."
6.	**3.2.P.5.1**	Justify for not including the test of dissolution in the specification of drug product, since the dissolution test is the part of BP monograph of doxycycline capsule.
7.	**3.2.P.5.2-3.2.P.5.3**	Justify how the product comply BP specification when the given assay procedure is different from the assay method specified in BP monograph. Further the verification studies has also been performed on assay procedure different from the method given in BP monograph.
8.	**3.2.P.6**	Provide certificate of analysis of reference standard /working standard used for testing of the drug product.

9.	**3.2.P.8**	Justify for not including the dissolution test in the stability studies of drug product since the dissolution test is recommended in BP monograph.

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate.	Submitted
2.	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.	Submitted
3.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Submitted
4.	Provide certificate of analysis of reference standard /working standard used for testing of the drug product.	Not submitted
5.	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."	Firm submitted the CDP report performed against the product Vibramycin Capsule of M/s. Pfizer Inc.
6.	Justify for not including the test of dissolution in the specification of drug product, since the dissolution test is the part of BP monograph of doxycycline capsule.	Firm submitted revised specification and analytical procedure of drug product. However the acceptance criteria of dissolution test is not in accordance with BP.
7.	Justify how the product comply BP specification when the given assay procedure is different from the assay method specified in BP monograph. Further the verification studies has also been performed on assay procedure different from the method given in BP monograph.	Firm submitted revised analytical verification report.
8.	Provide certificate of analysis of reference standard /working standard used for testing of the drug product.	Not submitted
9.	Justify for not including the dissolution test in the stability studies of drug product since the dissolution test is recommended in BP monograph.	Revised stability data submitted in which results of dissolution test was included but the acceptance criteria of dissolution test is not in accordance with BP.

Decision: Deferred for submission of following:

• **Justify for not adopting acceptance criteria of dissolution test of drug product in accordance with BP monograph of doxycycline capsule.** • **Provide certificate of analysis of reference standard /working standard used for testing of the drug substance and drug product.**		
962.	Name, address of Applicant / Importer	M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.
	Details of Drug Sale License of importer	License No:041 Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi. Address of Go down: Same as above Validity: 19-11-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized of CoPP certificate (No. 2105062) dated 27-05-2021 by the issuing authority Yiyuan Market Supervision and Administration of P.R. China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 26-05-2023.** GMP certificate issued by China Food and Drug Administration to M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. dated 13-06-2018 and valid till 12-06-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted agent & distributor agreement between M/s. Qingdao JidaBarr International Trade Co., Ltd., No.-2, B-1-4, Heilongjiang South Road, Qingdao City, China **(Exporter), M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.** and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter specifies that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☒ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.1739 dated 19-01-2022
	Details of fee submitted	PKR 150,030/-: DATED 03-01-2022
	The proposed proprietary name / brand name	BenzylPenicillin Sodium 500,000 IU Injection (0.5 Mega)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Benzylpenicillin Sodium eq. to Benzyl penicillin…0.5 Mega
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Beta-lactamase sensitive penicillins
	Reference to Finished product specifications	BP specification
	Proposed Pack size	10 vials/box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not confirmed
	For generic drugs (me-too status)	Not confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No.88 Yangzi Road Economic & Technological Development Zone Shijiazhuang City Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25℃±2, 60% RH±5%. The stability study data is till 24 months. Batch no. 891805901, 891805901, 891805901 Claimed 48 months but provided data of 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients,

		control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted. Pharmaceutical Equivalence established against the product of M/s. Shandong Lukang Pharmaceuticals Co. Ltd., China
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	7ml Type-II glass vial rubber stopper flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 36 months has submitted.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.

Decision of 326th meeting of Registration Board:

Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

Firm submitted the evidence of approval status of applied product in the reference regulatory agencies and details are as follows:

Firm submitted the evidence of RRA of CBGMEB (Netherland) https://www.geneesmiddeleninformatiebank.nl/ords/f?p=111:3::SEARCH:::P0_DOMAIN,P0_LANG,P3_RVG1:H,EN,120396 product Sodium benzyl penicillin Sandoz 500,000 IU, powder for solution for injection or infusion (Sandoz B.V. Sodium benzylpenicillin Sandoz® 500,000, 1,000,000, 5,000,000, 10,000,000 IU, powder for solution for injection or infusion).

Sodium benzylpenicillin Sandoz 500,000 IU, powder for solution for injection or infusion approved in the reference country CBGMEB (Netherland) with the label claim:

Each vial contains 500,000 IU (equivalent to approximately 0.3 g) 0.3 g, 300 mg benzylpenicillin as sodium salt. Each vial contains 19.3 mg sodium.

After the submission of above reference, application has been evaluated and shortcoming letter has been communicated to the firm. Later the applicant submits their response which is as under:

S.no.	Observations/Deficiencies/ Short-comings along with their reply from the Firm
1.	**According to the composition of finished product given in section 3.2.P.1 299.5 mg of benzyl penicillin sodium equivalent to benzyl penicillin 0.5 mega powder for injection is filled per vial while the reference product approved in CBGMEB (Netherland) claimed that Each vial contains 500,000 IU (equivalent to approximately 0.3 g) 0.3 g, 300 mg benzyl penicillin as sodium salt. Each vial contains 19.3 mg sodium. Comparing the label claim/ strength justify how the applied product is similar to the reference product.** Firm replied that "for International units and mass value following ratios apply: 1mg benzyl penicillin sodium is equivalent to 1670IU benzyl penicillin. 500,000 IU benzyl penicillin is equivalent to about 300mg benzyl penicillin. In general, 300mg benzyl penicillin sodium is considered to be equivalent to 500,000 IU Benzyl penicillin.

	The difference between the 299mg in our product with 300mg in the reference product may be because of rounding off. However the quantity of sodium content per vial is still not been addressed by the applicant.
2.	**Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.** Firm submitted the assay verification report of drug substance in accordance with BP monograph.
3.	**Details of Type and Quantity of diluents used for reconstitution for Benzyl Penicillin 0.5 Mega and 1 Mega is required.** Firm submitted the details of diluent and quantity of diluent used for reconstitution of applied product.
4.	**According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzyl penicillin content, justification is required in this regard.** **In continuation of point 3, Clarification is required that content of Penicillin is calculated in the assay of Drug product comparing the assay criteria of BP monograph in which the assay results are based on the quantity of Benzyl Penicillin.** In the response of above two queries, firm replied that "We, Reyoung Pharmaceutical Co., Ltd.(No.1 Ruiyang Road, Yiyuan County, Shandong, Province.P.R. China), hereby clarify that: In the monograph of current British Pharmacopeia, the product under registration is named as Benzylpenicilin for Injection as it mentioned in the Definition. Which is an aseptic filled product with sterile Benzylpenicillin Sodium. The strength of the product is expressed as per the content of penicillin (or Benzylpenicillin) (C16H18N2O4S) in Benzylpenicillin Sodium (C16H17N2NaO4). The content of penicillin is the same with content of benzylpenicillin. It's just a different way of writing. According to the requirements of DRAP and the description of BP monograph, we have revised the content in pharmaceutical equivalence report to be unified as "Benzyl penicillin". According to the Manufacturer Abroad that it is just a difference in written statement as writing *content of penicillin* is similar in meaning to the statement *content of Benzyl penicillin*, despite the fact that penicillin is broader term and the benzyl penicillin is one its variant.
5.	**Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzyl penicillin sodium injection, justification is required in this regard.** Firm claimed that "We performed all the validation studies according to BP 2018 monograph, BP2018 is the latest version prior to submission of registration dossier, all of the assay procedure validation items are consistent with BP2018".
6.	**Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph.** Firm submitted the stability studies of drug product in which again bacterial endotoxin test is not included.

Decision: Deferred for submission of following:

- **Clarify the composition of applied drug product relating the reference product particularly with respect to the content of sodium, since the mentioned label claim of applied product did not specify the sodium content.**
- **Clarification is required for quantify the content of Penicillin in the assay of Drug product comparing the assay criteria of BP monograph which gives the limit of Benzyl Penicillin.**
- **Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph.**

963.	Name, address of Applicant / Importer	M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.
	Details of Drug Sale License of importer	License No:041

		Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi. Address of Go down: Same as above Validity: 19-11-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized of CoPP certificate (No. 2105062) dated 27-05-2021 by the issuing authority Yiyuan Market Supervision and Administration of P.R. China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 26-05-2023. GMP certificate issued by China Food and Drug Administration to M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. dated 13-06-2018 and valid till 12-06-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted agent & distributor agreement between M/s. Qingdao JidaBarr International Trade Co., Ltd., No.-2, B-1-4, Heilongjiang South Road, Qingdao City, China (Exporter), M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter specifies that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☒ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.1740 dated 19-01-2022
	Details of fee submitted	PKR 150,030/-: DATED 03-01-2022
	The proposed proprietary name / brand	BenzylPenicillin Sodium for injection 1 mega

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Benzylpenicillin Sodium eq. to Benzyl penicillin…1 mega
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Beta-lactamase sensitive penicillin
	Reference to Finished product specifications	BP specification
	Proposed Pack size	10 vials/box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Benzyl penicillin sodium injection 1000,000 IU OF IMPORTER United international (Reg.no. 043024)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No.88 Yangzi Road Economic & Technological Development Zone Shijiazhuang City Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 24 months. Batch no. 891805901, 891805901, 891805901 Claimed 48 months but provided data of 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted. Pharmaceutical Equivalence established against the product of M/s. Shandong Lukang

		Pharmaceuticals Co. Ltd., China Benzyl penicillin Sodium for Injection (1mega)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	7ml Type-II glass vial rubber stopper flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 36 months has submitted.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit evidence of approval status of applied formulation in the approved reference regulatory agencies in the same strength i.e. 1,000,000 IU.	
2.	Clarify the strength of applied formulation, since you have applied for benzyl penicillin sodium injection 1,000,000 IU while the CoPP is of benzyl penicillin sodium for injection 1 mega. Please submit the conversion/equivalent calculation from 1,000,000 IU to 1 mega.	
3.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Analytical procedure of drug substance by drug substance manufacturer is different from the procedure specified in EP monogragh,Justify how the raw material comply EP specification as claimed in the batch analysis report.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.
5.	3.2.P.1	According to the composition of finished product given in section 3.2.P.1 599mg equivalent to benzyl penicillin 1mega powder for injection is filled per vial while the reference product approved in MHRA claimed that Each vial contains Benzylpenicillin sodium 600 mg (1 mega unit). Comparing the label claim/ strength justify how the applied product is similar to the reference product.
6.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product.
7.	3.2.P.2.2.1	According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzypenicillin content, justification is required in this regard.
8.	3.2.P.5.1	Clarify the content of penicillin in term of benzyl penicillin as recommended by BP monograph.
9.	3.2.P.5.3	Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzypenicillin sodium injection, justification is required in this regard.
10.	3.2.P.8	Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.		Submit evidence of approval status of applied formulation in the approved reference regulatory agencies in the same strength i.e. 1,000,000 IU. Firm submitted the reply in which they stated "As a generic drug product with many years of production experience, Benzyl penicillin sodium for injection has been registered in many countries and obtained registration qualification, which is consistent with the formulation registered in Pakistan this time". (As a reference they attached registration certificate of Ghana and Nigeria) However, the reference product approved in MHRA Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion contains: Benzyl penicillin Sodium 600 mg powder for solution for injection / infusion: Each vial contains 600 mg benzylpenicillin as sodium salt. Each vial contains 38.6 mg of sodium. Further the conversion details are mentioned in the SmPC of reference formulation is For international units (IU) and mass values, the following ratios apply: 1 mg benzylpenicillin sodium is equivalent to 1670 IU benzylpenicillin. 1 million IU benzylpenicillin is equivalent to 598.9 mg benzylpenicillin sodium. In general, 600 mg benzylpenicillin sodium is considered to be equivalent to 1 million IU benzylpenicillin.
2.		Clarify the strength of applied formulation, since you have applied for benzyl penicillin sodium injection 1,000,000 IU while the CoPP is of benzyl penicillin sodium for injection 1 mega. Please submit the conversion/equivalent calculation from 1,000,000 IU to 1 mega. Firm replied that 1,000,000 IU is equivalent to 1Mega.
3.	3.2.S.4.1	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Firm submitted the specification of drug substance by drug product manufacturer which is in accordance with BP.
4.	3.2.S.4.2	Analytical procedure of drug substance by drug substance manufacturer is different from the procedure specified in EP monograph, justify how the raw material comply EP specification as claimed in the batch analysis report. Firm submitted the analytical procedure of drug substance by drug product manufacturer which is inaccordance with EP monograph.
5.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer. Firm replied that we will submit later.
6.	3.2.P.1	According to the composition of finished product given in section 3.2.P.1 599mg equivalent to benzyl penicillin 1mega powder for injection is filled per vial while the reference product approved in MHRA claimed that Each vial contains Benzyl penicillin sodium 600 mg (1 mega unit). Comparing the label claim/ strength justify how the applied product is similar to the reference product. Firm submitted the calculation as followings: Potency of Benzyl Penicillin Sodium= 1670 IU/mg (Each 1mg of C16H17N2NaO4S is equivalent to 1670 penicillin units, prescribed in pharmacopeia. Quantity per vial= 1,000,000IU/1670 IU/mg =598.8mg=599mg Fill weight may vary based on potency of active ingredient.

		The difference between the "599mg" in our product with "600mg" in the reference product may be because of rounding.
7.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product. Firm replied that the reconstitution diluent are water for injection and 0.9% sodium chloride.
8.	3.2.P.2.2.1	According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzyl penicillin content, justification is required in this regard. Firm did not submit the relevant reply.
9.	3.2.P.5.1	Clarify that either the content of penicillin is calculated in the assay of drug product comparing the assay criteria BP monograph in which the assay results are based on the quantity of benzyl penicillin. Firm did not submit the relevant reply.
10.	3.2.P.5.3	Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzyl penicillin sodium injection, justification is required in this regard. Firm submitted the reply that it was a writing error and they have submitted the revised analytical procedure in accordance with BP. However, the revised analytical procedure was also not in accordance with BP as evident from the submitted report.
11.	3.2.P.8	Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph. Firm submitted the revised stability summary sheets in which Bacterial endotoxin test were included and the assay results are related to quantification of penicillin instead of Benzyl penicillin.

Decision of 329th meeting of Registration Board:

Deferred for the submission of following shortcomings/justifications:

- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance by drug substance manufacturer.
- Justify the assay testing of drug product comparing the assay test in BP monograph, wherein the assay of benzypenicillin is recommended while the firm performed the assay of penicillin**.**

Response of the Firm:

- **Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance by drug substance manufacturer.**

Firm submitted the verification report of drug substance performed by drug product manufacturer.

- **Justify the assay testing of drug product comparing the assay test in BP monograph, wherein the assay of benzyl penicillin is recommended while the firm performed the assay of penicillin.**

In the response of above query, firm replied that "We, Reyoung Pharmaceutical Co., Ltd.(No.1 Ruiyang Road, Yiyuan County, Shandong, Province.P.R. China), hereby clarify that: In the monograph of current British Pharmacopeia, the product under registration is named as Benzylpenicilin for Injection as it mentioned in the Definition. Which is an aseptic filled product with sterile Benzylpenicillin Sodium. The strength of the product is expressed as per the content of penicillin (or Benzylpenicillin) (C16H18N2O4S) in Benzylpenicillin Sodium (C16H17N2NaO4). The content of penicillin is the same with content of benzylpenicillin. It's just a different

way of writing. According to the requirements of DRAP and the description of BP monograph, we have revised the content in pharmaceutical equivalence report to be unified as "Benzyl penicillin". According to the Manufacturer Abroad that it is just a difference in written statement as writing *content of penicillin* is similar in meaning to the statement *content of Benzyl penicillin*, despite the fact that penicillin is broader term and the benzyl penicillin is one of its variant.		
Decision: Deferred for clarity regarding the results of assay of applied drug product comparing the declared label of BP monograph of Benzylpenicillin for Injection i.e. "95.0 to 105.0% of the content of benzylpenicillin stated on the label". Further, Clarify the composition of applied drug product relating the reference product particularly with respect to the content of sodium, since the mentioned label claim of applied product did not specify the sodium content.		
964.	Name, address of Applicant / Importer	M/s Grace Pharmaceuticals
	Details of Drug Sale License of importer	License No. 152 Address: Office no. 503, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan. Address of Go down: NA Validity: 21-10-2023 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name, address of manufacturer(s)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted notarized (notarized by Beijing Fangyuan Notary Public Office) copy of CoPP certificate (No: 20210127) dated 23-03-2021 issued by Beijing Municipal Medical Product Administration CHINA for Iodixanol injection 50ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned. Furthermore the CoPP was valid till 31-10-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beijing Beilu Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints M/s Grace Pharmaceuticals. To register their products in Pakistan. The authorization letter is valid till 30-04-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import

		☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 153 : 03-01-2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 5548215985
	The proposed proprietary name / brand name	Intrapaque 50 mL : 16g I Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Iodixanol …….50ml (50ml:16g I)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Medical Imaging Drug
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 VIAL
	Proposed unit price	N/A
	The status in reference regulatory authorities	Visipaque® 320mg Iodine/ml GE Healthcare AS USFDA APPROVED
	For generic drugs (me-too status)	Visipaque 320mgI/ml (50ml as per available data)(Reg.no.043052) M/s. Bayer
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	GE Healthcare As Lindesnesveien208, N0-4551 Lindesnes, Norway
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of IODIXANOL Injection instead of iodixanol API. The real time stability data is conducted at 30 °C±2, RH 65%±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the comparative study on quality of iodixanol injection (50ml:16mg(I) between reference preparation and self-made preparation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium borosilicate glass infusion bottle, strength: 50ml Bottle Pack: Halogenated butyl rubber stopper for injection (chlorinated), strength: 32mm Aluminum-plastic composite cover for infusion bottle, strength: 32mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. Accelerated Stability batches: R200101, R200102, R200103 Real Time Stability Batches: R200102 (18 months) R200103 (36 months)

VISIPAQUE
is indicated in for: 1.1 Intra-arterial Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) intra-arterial digital subtraction angiography (IA-DSA).
• (320 mg Iodine/mL) angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Pediatric patients less than 12 years of age
• (320 mg Iodine/mL) angiocardiography, cerebral arteriography, and visceral arteriography. 1.2 Intravenous Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) CT imaging of the head and body.
• (270 and 320 mg Iodine/mL) excretory urography.
• (270 mg Iodine/mL) peripheral venography.
• (320 mg Iodine/mL) coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease. Pediatric patients less than 12 years of age
• (270 mg Iodine/mL) CT imaging of the head and body.
• (270 mg Iodine/mL) excretory urography.
Evaluation by PEC:
Firm has to be submit requisite fee for imported product, since the Me-Too of 50ml is available in the record.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.	
2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity,*

		accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".*
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*
7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.
8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy".*

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.		Firm submitted the copy of CoPP certificate no.20230045 issue dated 13-02-2023 by Biejing Municipal Medical Product Administration, which is valid till 12-02-2025.
2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug	Firm submitted the specification and analytical procedure of drug substance by drug product manufacturer i.e. M/s. Beijing Beilu Pharmaceutical Co., Ltd, while drug substance

		substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".	specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug substance manufacturer i.e. M/s. GE Healthcare As. has not been submitted.
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm replied that "Bielu analyzes API according to USP compendial method. So Bielu Pharmaceuticals did not conduct methodological validation.
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*	Firm submitted Batch analysis report of drug substance only by drug product manufacturer.
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is*	Firm has not submitted the COA of reference standard of iodixanol.

		recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".	
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*	Firm submitted the requisite details.
7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.	Firm submitted the stability data of drug substance submitted by drug product manufacturer (M/s. Biejing Bielu Pharmaceuticals Co. Ltd., China instead of M/s. GE Health care, Norway) till 18 months while the claimed shelf life mentioned on the document is 36 months.
8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.	Firm submitted the details of reference product i.e. Reference preparation Manufacturing: GE Healthcare As Expiry date: 36 months.
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity,*	Firm submitted the analytical method validation report of assay procedure of drug product.

		repeatability (method precision) and accuracy".	

Decision of 333rd meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit specification and analytical procedure of drug substance used for analysis by drug substance manufacturer.
- Provide analytical verification report of drug substance performed by drug product manufacturer.
- Submit Certificate of analysis of API from drug substance manufacturer.
- Submit complete stability data of drug substance conducted at both accelerated and long term condition till the claimed re-test date, performed by the drug substance manufacturer.

Response of the Firm:
Previously firm submitted the registration application claiming drug substance manufacturer of their applied product was GE Healthcare A.S. Lindesnesveien208, N0-4551 Lindesnes, Norway and accordingly submit the requisite documents of drug substance part. Now in this reply firm change the source of API from G.E.Healthcare, Norway to M/s. Zhejiang Starry Pharmaceuticals Co. Ltd. No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju Zhejiang, China without any clarification/justification and only submitted the reply of queries on the basis of which case was deferred in 333rd meeting of Registration Board, instead of submitting complete new dossier in accordance with new source of API along with requisite fee.

Decision: Deferred for clarification regarding the change of source of API Manufacturer from M/s. G.E. Healthcare, Norway to M/s. Zhejiang Starry Pharmaceuticals Co. Ltd. No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju Zhejiang, China. Further, submit complete product part of module-3 in-line with new source of API manufacturer along with requisite fee.

965.	Name, address of Applicant / Importer	M/s Grace Pharmaceuticals
	Details of Drug Sale License of importer	License No. 152 Address: Office no. 503, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan. Address of Go down: NA Validity: 21-10-2023 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name, address of manufacturer(s)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No: 20210349) dated 18 Aug, 2021 issued by Beijing Municipal Medical Product Administration CHINA for Iodixanol injection 100ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned. Furthermore the CoPP was valid till 12-12-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beijing Beilu Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints M/s Grace Pharmaceuticals. To register their products in Pakistan. The authorization letter is valid till 30-04-2026.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.5508 : 28-02-2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 5548215985 dated 10-02-2022
	The proposed proprietary name / brand name	Intrapaque 100mL : 32g I Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Iodixanol…32g(I)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Medical Imaging Drug
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 VIAL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Visipaque® 320mg Iodine/ml GE Healthcare AS USFDA APPROVED
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	GE Healthcare As Lindesnesveien208, N0-4551 Lindesnes, Norway
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of IODIXANOL Injection instead of iodixanol API. The real time stability data is conducted at 30 °C±2, RH 65%±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the comparative study on quality of iodixanol injection (50ml:16mg(I) between reference preparation and self-made preparation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium borosilicate glass infusion bottle, strength: 100ml Bottle Pack: Halogenated butyl rubber stopper for injection (chlorinated), strength: 32mm Aluminum-plastic composite cover for infusion bottle, strength: 32mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of 50ml. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH.

VISIPAQUE
is indicated in for: 1.1 Intra-arterial Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) intra-arterial digital subtraction angiography (IA-DSA).
• (320 mg Iodine/mL) angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Pediatric patients less than 12 years of age
• (320 mg Iodine/mL) angiocardiography, cerebral arteriography, and visceral arteriography. 1.2 Intravenous Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) CT imaging of the head and body.
• (270 and 320 mg Iodine/mL) excretory urography.
• (270 mg Iodine/mL) peripheral venography.
• (320 mg Iodine/mL) coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease. Pediatric patients less than 12 years of age
• (270 mg Iodine/mL) CT imaging of the head and body.
• (270 mg Iodine/mL) excretory urography.
Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.		Firm submitted the requisite documents.

2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".	Firm submitted the specification and analytical procedure of drug substance by drug product manufacturer i.e. M/s. Beijing Beilu Pharmaceutical Co., Ltd, while drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug substance manufacturer i.e. M/s. GE Healthcare As. has not been submitted.
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm replied that "Bielu analyzes API according to USP compendial method. So Bielu Pharmaceuticals did not conduct methodological validation.
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*	Firm submitted Batch analysis report of drug substance only by drug product manufacturer.
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of*	Firm has not submitted the COA of reference standard of iodixanol.

		Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".	
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*	Firm submitted the requisite details.
7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.	Firm submitted the stability data of drug substance submitted by drug product manufacturer (M/s. Biejing Bielu Pharmaceuticals Co. Ltd., China instead of M/s. GE Health care, Norway) till 18 months while the claimed shelf life mentioned on the document is 36 months.
8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.	Firm has not submitted the requisite information.
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a*	Firm submitted the analytical method validation report of assay procedure of drug product.

		demonstration of specificity, repeatability (method precision) and accuracy".	
10.	3.2.P.8	Provide details/ batch numbers of stability batches of applied formulation, since the batch no. mentioned on the stability summary sheets is same as for 50ml.	Firm submitted the stability data of iohexol instead of stability data of iodixanol (100ml).

Decision of 333rd meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit specification and analytical procedure of drug substance used for analysis by drug substance manufacturer.
- Provide analytical verification report of drug substance performed by drug product manufacturer.
- Submit Certificate of analysis of API from drug substance manufacturer.
- Submit complete stability data of drug substance conducted at both accelerated and long term condition till the claimed re-test date performed by the drug substance manufacturer.
- Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.
- Submit stability data of drug product (100ml volume size) performed at both accelerated and long term condition till the claimed shelf life.

Response of the Firm:

Previously firm submitted the registration application claiming drug substance manufacturer of their applied product was GE Healthcare A.S. Lindesnesveien208, N0-4551 Lindesnes, Norway and accordingly submit the requisite documents of drug substance part. Now in this reply firm change the source of API from G.E.Healthcare, Norway to M/s. Zhejiang Starry Pharmaceuticals Co. Ltd. No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju Zhejiang, China without any clarification/justification and only submitted the reply of queries on the basis of which case was deferred in 333rd meeting of Registration Board, instead of submitting complete new dossier in accordance with new source of API along with requisite fee.

Decision: Deferred for clarification regarding change of source of API Manufacturer from M/s. G.E. Healthcare, Norway to M/s. Zhejiang Starry Pharmaceuticals Co. Ltd. No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju Zhejiang, China. Further, submit complete product part of module-3 in-line with new source of API manufacturer along with requisite fee.

966.	Name, address of Applicant / Importer	M/s. M&M Pharma Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore
	Details of Drug Sale License of importer	License No:0000009412 Address: Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore Address of Go down: Same as above Validity: 19-10-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s. HLL Lifecare Limited (A. Govt. of India Enterprise) survey no. 76/3+7+8+9,75/1+2+3,59/1&2 Kanagala-591225, Dist: Belagavi. Karnataka India
	Name, address of manufacturer(s)	M/s. HLL Lifecare Limited (A. Govt. of India Enterprise) survey no. 76/3+7+8+9,75/1+2+3,59/1&2 Kanagala-591225, Dist: Belagavi. Karnataka India
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted copy of CoPP certificate (GSC No. DD0990000017860) dated 22-11-2019 by the issuing authority Drug Control Department Karnataka India. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 25-06-2022. Firm submitted WHO public inspection report related to the WHO product no. RH065 Levonorgestrel 1.5 mg Tablet.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization in the name of M/s. M&M Pharma Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore from M/s. HLL Life care Limited, Karnataka ,India to register/market the product Oral Contraceptive pills & Emergency Contraceptive pills with Ministry of Health Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.2812 dated 28-01-2022
	Details of fee submitted	PKR 100,030/-: DATED 09-01-2020 (Differential fee required)
	The proposed proprietary name / brand name	UNIPILL Tablet 1.5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levonorgestrel…..1.5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Progestogens
	Reference to Finished product specifications	BP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Not confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Qinhuangdao Zizhu Pharmaceutical Co. Ltd. No.10 Longhai Road, Economic and Technological Development Zone, Qinhuangdao City, Hebei Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug product instead of stability data of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted. Pharmaceutical Equivalence established against the comparator product of Plan B One-Step (Levonorgestrel) Tablet 1.5mg of M/s. Gedeon Richter Ltd., Budapest , Hungary and comparative dissolution studies has also conduct against the same comparator product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu-PVDC COATED PVC foil blisters
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 60 months has submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit original ,valid and legalized CoPP of drug product, since you have submitted the copy of CoPP.	
2.	Submit valid Drug Sale License of ,since the submitted DSL was expired on 19-10-2022.	

3.	3.2.S.4.2	Justify for performance of assay using UV Spectrophotometer while the EP recommends Potentiometric titration method for assay testing of drug substance.
4.	3.2.S.7	Submit stability data of drug substance performed at accelerated and long term stability conditions till the claimed shelf life/re-test period, since the submitted data in section 3.2.S.7 is of drug product instead of drug substance.
5.	3.2.P.1	According to the WHO assessment report of applied product lactose monohydrate is of bovine origin. Please submit the details related to the originating source of lactose monohydrate .
6.	3.2.P.5.2	Justify for keeping the detection wavelength 243nm in the chromatographic condition of dissolution testing of drug product comparing the detection wavelength recommended in the BP monograph of levonorgestrel tablet i.e.220nm.
7.	3.2.P.8	Justify the variation observed in acceptance criteria of dissolution while performing the stability data of drug product. As evident from the submitted stability data, at certain time points the acceptance criteria of dissolution has set at Qvalue-75% of the active substance release in 60 min while at other time points dissolution criteria has kept at NLT 80% in 30minutes.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit original ,valid and legalized CoPP of drug product, since you have submitted the copy of CoPP.	Firm submitted the copy of CoPP certificate no. DCD/SPL.CELL-I/CR-338/2022-23 dated 03-03-2023 certifying authority is drug control department Bangalore India with the validity of 28-06-2023. Further applicant commit that they submit original CoPP duly attested will be submitted within a period of one month time.
2.	Submit valid Drug Sale License of ,since the submitted DSL was expired on 19-10-2022.	Submitted
3.	Justify for performance of assay using UV Spectrophotometer while the EP recommends Potentiometric titration method for assay testing of drug substance.	Firm replied that "The assay method for Levonorgestrel API as per the European Pharmacopoeia is by using Potentiometric method. Please note that the USP has mentioned UV spectrophotometry method for the analysis of assay. We have selected UV spectrophotometry method as mentioned in USP over potentiometric method for better control on the variables, thereby improving the accuracy and repeatability. This UV spectrophotometry method is also assessed and improved by WHO pre-qualification team". However, drug substance manufacturer claimed EP specification for drug substance in the submitted dossier"
4.	Submit stability data of drug substance performed at accelerated and long term stability conditions till the claimed shelf life/re-test period, since the submitted data in section 3.2.S.7 is of drug product instead of drug substance.	Submitted
5.	According to the WHO assessment report of applied product lactose monohydrate is of	Manufacturer Abroad submitted Regulatory Information sheet for confirmation of

	bovine origin. Please submit the details related to the originating source of lactose monohydrate .	originating source of Lactose monohydrate i.e. Bovine source.
6.	Justify for keeping the detection wavelength 243nm in the chromatographic condition of dissolution testing of drug product comparing the detection wavelength recommended in the BP monograph of levonorgestrel tablet i.e.220nm.	M/s. HLL Lifecare Limited replied that the analytical method for the dissolution analysis of Levonorgestrel in the Levonorgestrel tablets developed in-house in HLL and is taken from the Levonorgestrel tablets monograph Levonorgestrel tablet monograph of BP with change in detection wavelength from 220nm to 243nm. It is observed that at 220nm blank peaks and interference near to main principal peak and more disturbances observed in base line. Due diligence supported by technical evidences were carried out during method development for the determination of appropriate wavelength for Levonorgestrel in the dissolution media. This methodology also includes spectral scanning by UV spectrophotometer as well as by HPLC in the range 200-400nm. It was observed that at 243nm there was no interference observed from diluent or any other base line disturbances.
7.	Justify the variation observed in acceptance criteria of dissolution while performing the stability data of drug product. As evident from the submitted stability data, at certain time points the acceptance criteria of dissolution has set at Qvalue-75% of the active substance release in 60 min while at other time points dissolution criteria has kept at NLT 80% in 30minutes.	M/s. HLL Lifesciences replied that the initial set acceptance criteria of dissolution for release and shelf life for Levonorgestrel 1.5mg Tablet was "not less than 75%(Q) in 60 minutes". The dissolution limit was later revised for both release and shelf life based on the dissolution profile of biobatch as recommended by the WHO PQ team for the product during dossier assessment in September,2016. The revised dissolution acceptance criteria i.e. not less than 80%(Q) IN 30minutes was made effective from the 12th month real time stability study onward.

Decision OF 331st Meeting of Registration Board:

Deferred for the submission of following shortcomings:

- According to the submitted documents drug substance complied EP specification, while you have performed the assay test in accordance with USP specification according to your submitted reply, so, clarification is required in this regard.
- Justify for not adopting the same detection wavelength for the assay of drug product as recommended in the BP monograph of Levonorgestrel tablet.

Response of the Firm:

- **According to the submitted documents drug substance complied EP specification, while you have performed the assay test in accordance with USP specification according to your submitted reply, so, clarification is required in this regard.**

Applicant submitted the following response of Manufacturer Abroad:

HLL Reply: The assay method for Levonorgestrel API as per the European Pharmacopoeia is by using Potentiometric method. Please note that the US Pharmacopoeia has mentioned UV Spectrophotometry method for the analysis of assay. We have selected UV spectrophotometry method as mentioned in USP over potentiometric method for better control on the variables, thereby improving the accuracy and repeatability. This UV Spectrophotometry method is also assessed and approved by WHO pre-qualification team.

- **Justify for not adopting the same detection wavelength for the assay of drug product as recommended in the BP monograph of Levonorgestrel tablet.**

Applicant submitted the following response of Manufacturer Abroad:

It is observed that at 220 nm, blank peaks had interference near to main principal peak and more disturbances observed in base line. Due diligence supported by technical evidences were carried out during method development for the determination of appropriate wavelength for Levonorgestrel in the dissolution media. This methodology also includes spectral scanning by UV spectrophotometer as well as by HPLC in the range of 200-400 nm. It was observed that at 243 nm, there was no interferencesobserved from diluent or any other base line disturbances, hence it was concluded that, 243 nm is the most appropriate wavelength for the analysis of Levonorgestrel tablets for dissolution. Method is fully validated as per the ICH Q2 (R1) guidelines.

Decision: Approved with BP specification as per Policy for inspection of Manufacturer abroad.Further, the address of Marketing Authorization Holder will be as per the *WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS* i.e. M/s. HLL Lifecare Limited (A Government of India Enterprise) Unipill Block Kanagala Belagavi (District) Karnataka India.

967.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0058-066904D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 24-02-2023. Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name, address of manufacturer(s)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. 20210368) dated 08-2021 issued by CCPIT for compound alpha ketoacid tablet. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-08-2023.

	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Hebei tiancheng pharmaceutical Co. Ltd. The letter species that the manufacturer appoints M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan to register their products in Pakistan. The authorization letter is valid till 08-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.3529 dated 07-02-2022
	Details of fee submitted	PKR 150,030/-: 02-11-2021
	The proposed proprietary name / brand name	**Ketogen tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Compound α- Ketoacid …….0.63g
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	amino acid , including combination with polypeptide
	Reference to Finished product specifications	In house
	Proposed Pack size	20 tablets/blister, 5 blisters/box
	Proposed unit price	Rs. 3450/- box
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Not confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 2 batches is for 12 months while the stability study data for 3rd batch is for 9 months only.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
2.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply of the Firm:
Firm submitted the evidence of approval status of applied formulations in the following in reference regulatory agencies:

No.	Brand name	Country	MA Holder / Manufacturer	Formulation
I	Ketosteril	RMS Portugal CMS Belgium (BE), Denmark (DK), Spain (ES),	Fresenius Kabi Deutschland GmbH	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg

		Finland (FI), Croatia (HR), Italy (IT), Netherlands (NL), Norway (NO), Sweden (SE), Slovenia (SI)		Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg Phenylalanine Calcium, Alfa-Keto- 68 mg Hydroxymethionine Calcium, Alfa - 59 mg Tyrosine 30 mg
2	KETOSTERIL	Romania	FRESENIUS KABI DEUTSCHLAND GMBH - GERMANIA	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg
3	Ketosteril Tabletten	Germany	FRESENIUS KABI DEUTSCHLAND GMBH - GERMANIA	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg Phenylalanine Calcium, Alfa-Keto- 68 mg Hydroxymethionine Calcium, Alfa - 59 mg Tyrosine 30 mg

After the confirmation of approval status of applied formulation in the above given reference agencies, complete dossier has been evaluated and accordingly shortcoming letter has communicated to the firm. Firm submitted following reply in response of the shortcoming letter:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
Clarification is required related to the strength of tablet i.e. 0.63g mentioned in the relevant section, since the innovator product do not mention the strength of tablet as it is a combination product. In the response of above query firm submitted the clarification letter from the Finished Product Importer i.e. Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china, in which they stated that "The Applied Product (Compound α-Ketoacid Tablets, manufactured by Hebei Tiancheng Pharmaceutical Co., Ltd.) contains ten active substances the formulation of which is consistent with that of the Innovator Drug (Ketosteril). The formulation of Applied Product and Ketosteril are shown in the table below.			

No.	Ingredients	Each tablet contains:

		Applied Product	Ketosteril
1	α-Ketoleucine calcium	101mg	101mg
2	α-Ketovaline calcium	86mg	86mg
3	α-ketophenylalanine calcium	68mg	68mg
4	D L-α-ketoisoleucine calcium	67mg	67mg
5	D L-α-hydroxymethionine calcium	59mg	59mg
6	L-lysine acetate	105mg	105mg
7	L-threonine	53mg	53mg
8	L-tryptophan	23mg	23mg
9	L-histidine	38mg	38mg
10	L-tyrosine	30mg	30mg
Total		630mg	630mg

The strength of the finished product is specified as the weight (or potency) or content of the active substances as per the regulation of NMPA (National Medical Product Administration, China). Due to the Applied Product contains more active substances, the strength is specified as the weight of the active substances, 0.63g, in the dossier.

1.	1.5.6	Justify how you have claimed USP specification for the applied formulation when the official monograph is not present in USP.	Firm replied that the specification of applied is in-House standard.

Lysine Acetate

Justify for using API complying in-house specification when the official monograph of lysine acetate is present in USP.

Firm replied that The specifications of Lysine Acetate are ChP. For the amino acids such as Lysine Acetate, Chinese manufacturer can only purchase the APIs complied with ChP. Based on the stability results, the APIs complied with ChP can ensure the quality of the finished product.

Applied specification of L-Lysine Acetate	USP specification of L-Lysine acetate
Identification Infrared Absorption IR spectrum of the sample should be concordant with standard.	Identification Infrared Absorption IR spectrum of the sample should be concordant with standard.
Specific Rotation Between +8.5° and +10.0°.	Optical Rotation: Acceptance criteria: +8.4° to +9.9°
Transmittance T430 Clear and colourless. Not less than 98.0 %	NA
Chloride Not more than 0.02 %	Chloride: NMT 0.05%
Ammonium Not more than 0.02 %	NA
Sulfate Not more than 0.02 %	Sulphate : NMT 0.03%
Iron Not more than 10 ppm	Iron: NMT 30 ppm
Heavy metals Not more than 10 ppm	NA
Arsenic Not more than 1.0 ppm	NA
Loss on drying Not more than 0.20 %	LOSS ON DRYING: it loses NMT 0.2% of its weight.
Residue on ignition Not more than 0.10 %	Residue on Ignition: NMT 0.4%
Chromatographic Purity i) Any individual impurity ii) Total impurities Not more than 0.5 % Not more than 2.0 %	Related Compounds: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*. Individual impurities: NMT 0.5% Total impurities: NMT 2.0%
Assay (on anhydrous basis) 98.5 to 101.0 %	Assay: Acceptance criteria: 98.0%–102.0% on the dried basis (Direct Titration)
Residual Solvent	NA

2.	3.2.P.2.2.1	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted the pharmaceutical equivalence report in which all the quality parameters are included as per the specification of finished product. Further, the applied product (Compound α, -ketoacid Tablets) is a generic drug, the reference product is Ketosteril from Fresenius. The dosage forms, route of administration and active substances of applied product (Compound α, -ketoacid Tablets) is identical with those of Innovator drug. The quality between the applied product and reference product is comparable.
3.	3.2.P.2.2.1	Justify for not performing the comparative dissolution profiling study of individual amino acids.	Firm replied that "According to the specification for Compound Alpha-Ketoacid Tablets published by the Chinese NMPA, only the dissolution test for ketoanalogue calcium is required. Therefore, manufacturer instead of carrying out dissolution study of individual amino acid, performed comparative dissolution study of each ketoanalogue calcium".
4.	3.2.P.5.2	Justify for not including the dissolution profiling of individual amino acids in the release specification of finished drug product.	Firm replied that "According to the specification for Compound Alpha-Ketoacid Tablets published by the Chinese NMPA, only the dissolution test for ketoanalogue calcium is required, dissolution for each amino acid is not required".
5.	3.2.P.8	Submit complete stability data of drug product till the claimed shelf , since you have only submitted the detail of stability batches.	Firm submitted the stability data of batches 11101401,11101402,1110140 performed both at accelerated and long term conditions. However, the stability data is not on the letter head of manufacturer, without owned/signed by any technical personnel neither the stability conditions were mentioned on individual stability table of each batches.

Decision of 330th meeting of Registration Board:
Deferred for submission of detailed analytical procedure of dissolution testing of individual amino acid used in the formulation along with the stability data of drug product which includes the result of dissolution testing of each amino acid included in the applied formulation. Further, Comparative dissolution profiling data which includes the release profiling study of all the amino acids used in the applied formulation.

Response of the Firm:
Firm in their reply submitted the COA of innovator product i.e. Ketosteril Tablet in which the results of dissolution profiling of only calcium ketoanaolgue has been mentioned, which reflect that innovator product has also not performed the dissolution testing of individual amino acid used in the formulation.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

Registration Application Withdrawal Request by M/s. Citi Pharma Pvt. Ltd., Kasur:

M/s. Citi Pharma Pvt. Ltd. requested for withdrawal of registration application of following products vide letter no. CP/FM/2024/001 dated 01-01-2024 and letter no. CP/FM/2024/002 dated 01-01-2024, which were defer in 323rd meeting of Registration Board. In their letter firm stated that "we citi Pharma Pvt. Ltd. writing to inform you about a situation regarding the misalignment of documents related to a product that was submitted to DRAP Pakistan. Due to this issue, I would like to formally request the withdrawal of the following products from the system.

1. **Roxime Injection 250mg**
2. **Roxime Injection 750mg**
3. **Roxime Injection 1.5g**
4. **Citi-Pime Injection 500mg**
5. **Citi-Pime Injection 1g**
6. **Citi-Pime Injection 2g**

Detail of the case of above-mentioned products presented in 323rd meeting of Registration Board is as under:

968.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited Lahore
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Lahore Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23136 dated 16/08/2022
	Details of fee submitted	PKR 30,000/-: dated 27/05/2022
	The proposed proprietary name / brand name	Citi-Pime Injection IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL and Arginine Eq. to Cefepime 2g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 2g by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Maxum Injection 2g (Reg.no. 090510) of M/s. Curexa Health (Pvt.) Ltd. Plot No. 517, Sunder Industrial Estate, Lahore
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.

	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefepime HCL and Arginine Eq. to Cefepime is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH CEIV/IB1203011 36 MONTH CEIV/IB1203012 12 MONTH CEIV/IB1203013 Not submitted Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: CEIV/IB1203011/ CEIV/IB1203012/ CEIV/IB1203013
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Maxum Injection 2g by Highnoon pharmaceuticals performing quality tests (Identification, pH , Assay, Constituted Solution, Uniformity of dosage form,sterility,BET).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Kopran Research Laboratories Ltd India
API Lot No.	CFM-2104004
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Cef-P-001 (on covering page) TC008-01 (on stability data sheet) TC006 (on audit trail report)	Cef-P-001 (on covering page) TC008-01 (on stability data sheet) TC006 (on audit trail report)	Cef-P-001 (on covering page) TC008-01 (on stability data sheet) TC006 (on audit trail report)
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	26-09-2021	26-09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Deficiencies/ Short-comings
• Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2. • Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" • Submit complete long-term stability data of all three batches of drug substance, complete data of batch no. CEIV/B1203011 has only been submitted in section 3.2. S.7. • Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".

- Justify why pharmaceutical equivalence was performed against comparator product instead of using innovator / reference product.
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided". Since the submitted flow diagram of manufacturing procedure is of different drug product (cefotaxime sodium) instead of cefepime.
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.
- Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.
- Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the stability data, stability study has performed in the year 2022 whereas the submitted chromatograms and audit trail reports were of 2021, clarification required in this regard.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
- In-use stability studies of reconstituted injection are required along with proposed in-use storage statement and in-use shelf-life.
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Decision of 323rd meeting of Registration Board:
Deferred for submission of reply of above-cited shortcomings within six month.

969.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.11609 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Citi-Pime Injection 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L- Arginine Eq. to Cefepime 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 1g by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 1g by Global Pharmaceuticals, Reg. No. 046016
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefepime HCL with L-Arginine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure

		(including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand that is Zepime Injection 1g by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC006-001	TC006-002	TC006-003
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	02-2023	02-2023	02-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Kopran Research laboratories,India vide Dy. No. 6176 Dated: 16-04-2021. Invoice attested vide Dy.no. 6017/2021 DRAP dated: 22-04-2021in which exporter was M/s. Kopran Research laboratories, India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.1 3.2. S.4.2	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	3.2. S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.7	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	3.2. P.2.6	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"	Firm has not submitted the reply in response of this query.
5.	3.2. P.3.1	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process

		procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.	submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.
6.	3.2.P.5.2	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.
7.	3.2.P.5.3	Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	Firm has not given the reply in response of this query.
8.	3.2.P.5.4	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	3.2.P.6	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has submitted the reply in response of this query.
10.	3.2.P.8	Submit the stability data sheet of cefepime injection, since the	Firm stated that rectified and corrected stability data sheets are submitted.

		submitted sheets are of ceftriaxone.	
11.	3.2.P.8	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have submitted the stability data of real time study till 24month.	Firm stated that rectified and corrected stability data sheets are submitted. However, the firm submitted the raw data sheets of batch no. TC006-01, TC006-02, TC006-03.
12.		1. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 2. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. 3. Provide Reference of previous approval of applications with stability study data of the firm (if any) 4. Documents for the procurement of API with approval from DRAP (in case of import). 5. Provide compliance Record of HPLC software 21CFR &	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

		audit trail reports on product testing. 6. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 7. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 8. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision of 321st meeting of Registration Board:

- Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.
- Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.
- Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.
- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.
- Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.
- Batch analysis report of all three trial batches, in which all the quality test should be included that are specify in USP monograph of Cefepime injection.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Reply of the Firm:

Sr.no.	Decision of Registration Board	Response of Firm
1.	Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm submitted the specification and analytical procedure of drug substance by drug substance manufacturer instead from drug product manufacturer.
2.	Analytical method verification report of drug substance	Firm submitted the analytical verification report from which it is evident that the performance of accuracy

	performed by drug product manufacturer.	parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
3.	Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.	submitted
4.	Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.	submitted
5.	Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.	Not submitted
6.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.	Submitted
7.	Analytical method verification report of assay testing of drug product ,in compliance of USP monograph of Cefepime Injection	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
8.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.	Firm submitted the batch analysis report of three trial batches (TC006-001,TC006-002,TC006-003), Further the stability data sheet of real time stability study and COA of individual time points were of trial batches TC007-001,TC007-02,TC007-03.
9.	• Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the form-6 bearing the dy.no. 6176 dated 16-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine. Firm submitted the commercial invoice bearing the dy.no. 6017/2021 DRAP dated 22-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine.
10.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	As per the submitted raw data sheets and chromatograms it is evident that firm has not applied the chromatographic condition with reference to mobile phase program, injection volume and sample conc. as recommended by USP.
11.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3	Not submitted

Decision of 323rd meeting of Registration Board:

Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.**
- **Manufacturer will provide analytical method verification studies for drug substance by drug product manufacturer as per USP including specificity, accuracy and precision before the issuance of registration letter.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.**
- **Clarification required for not applied the same chromatographic condition for assay testing of drug product as recommended by USP monograph of cefepime injection, as evident from the submitted raw data sheets and chromatograms of stability batches.**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3**

970.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11608 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Citi-Pime Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L-Arginine Eq. to Cefepime 500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 500mg by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 500mg by Global Pharmaceuticals, Reg. No. 046015
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd,Maharashtra, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefepime for injection is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zepime Injection 500mg by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC006-001	TC006-002	TC006-003

Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	02-2023	02-2023	02-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Kopran Research laboratories, India vide Dy. No. 6176 Dated: 16-04-2021. Invoice attested vide Dy.no. 6017/2021 DRAP dated: 22-04-2021in which exporter was M/s. Kopran Research laboratories, India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Firm
1.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry*	Firm has not submitted the reply in response of this query.

	powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	
5.	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.
6.	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.
7.	Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	Firm has not given the reply in response of this query.
8.	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has submitted the reply in response of this query.
10.	Submit the stability data sheet of cefepime injection, since the submitted sheets are of ceftriaxone.	Firm stated that rectified and corrected stability data sheets are submitted.
11.	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have	Firm stated that rectified and corrected stability data sheets are submitted. However, the firm submitted the raw data sheets of batch no. TC006-01, TC006-02, TC006-03.

	submitted the stability data of real time study till 24month.	
12.	9. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 10. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. 11. Provide Reference of previous approval of applications with stability study data of the firm (if any) 12. Documents for the procurement of API with approval from DRAP (in case of import). 13. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. 14. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 15. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 16. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

Decision of 321st meeting of Registration Board:

- Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.
- Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.
- Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.
- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.
- Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.
- Batch analysis report of all three trial batches, in which all the quality test should be included that are specify in USP monograph of Cefepime injection.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Reply of the Firm:

Sr.no.	Decision of Registration Board	Response of Firm
1.	Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm submitted the specification and analytical procedure of drug substance by drug substance manufacturer instead from drug product manufacturer.
2.	Analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
3.	Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.	submitted
4.	Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.	submitted
5.	Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.	Not submitted
6.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.	Submitted
7.	Analytical method verification report of assay testing of drug product ,in compliance of USP monograph of Cefepime Injection	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
8.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.	Firm submitted the batch analysis report of three trial batches (TC007-001,TC007-002,TC007-003).
9.	• Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the form-6 bearing the dy.no. 6176 dated 16-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine. Firm submitted the commercial invoice bearing the dy.no. 6017/2021 DRAP dated 22-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine.
10.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective	As per the submitted raw data sheets and chromatograms it is evident that firm has not applied the chromatographic condition with reference to mobile phase gradient program,

	chromatograms separately for each time point.	injection volume and sample conc. as recommended by USP.
11.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3	Not submitted

Decision of 323rd meeting of Registration Board:
Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.**
- **Manufacturer will provide analytical method verification studies for drug substance by drug product manufacturer as per USP including specificity, accuracy and precision before the issuance of registration letter.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.**
- **Clarification required for not applied the same chromatographic condition for assay testing of drug product as recommended by USP monograph of cefepime injection, as evident from the submitted raw data sheets and chromatograms of stability batches.**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3**

971.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 21164 dated 27-07-2022	
	Details of fee submitted	**PKR 30,000/-**	**dated 30-04-2022(93609397821)**
	The proposed proprietary name / brand name	Roxime Injection 250mg IV/IM	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 250 mg	
	Pharmaceutical form of applied drug	Injection IV/IM	
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin	
	Reference to Finished product specifications	**USP Specifications**	
	Proposed Pack size	1X10ml	
	Proposed unit price	As per rule	
	The status in reference regulatory authorities	**Zinacef 250 mg, IV/IM, MHRA, UK.**	
	For generic drugs (me-too status)	Dowcef 250 mg IV/IM, Martin Dow.	

	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 250 mg IV/IM (GSK Pakistan) (Batch no. 305 U) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterilty and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri011-001	Tri011-002	Tri011-003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Description
1	**2.3.P.1**	Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product.
2	**2.3.P.2.6**	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.
3	**2.3.R.1.1**	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3

4	**3.2.S.4**	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • COA of primary / secondary reference standard including source and lot number shall be provided.
5	**3.2.S.7**	• Significant change in accelerated stability studies of Drug substance manufacturer batch no 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and 848 µg/mg to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stability studies data
6	**3.2.P.3**	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been provided. Justification required. Furthermore, in Standard manufacturing procure preparation of solution, filtration and filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Taxime. Justification shall be submitted. • The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.
7	**3.2.P.5**	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Testing procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Detailed analytical procedures used for testing the drug product shall be provided.
8	**3.2.P.7**	Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials.
9	**3.2.P.8**	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotometer method. However, in stability studies HPLC chromatograms are provided, which are not in accordance with USP official monograph. As in USP monograph Orcinol in water containing 1.5 mg per mL has been used as internal standard and the resolution, *R*, between the analyte and internal standard peaks is not less than 3.5. However, in provided chromatograms there is no peak of Orcinol. Justification required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Please provide Certificate of analysis of API which is actually used in manufacturing of product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

		• Documents for the procurement of API with approval from DRAP (in case of import). • Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

972.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 21165 dated 27-07-2022	
	Details of fee submitted	**PKR 30,000/-**	**dated 30-04-2022(57293016)**
	The proposed proprietary name / brand name	Roxime Injection 750mg IV/IM	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 750 mg	
	Pharmaceutical form of applied drug	Injection IV/IM	
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin	
	Reference to Finished product specifications	**USP Specifications**	
	Proposed Pack size	1X10ml	
	Proposed unit price	As per rule	
	The status in reference regulatory authorities	**Zinacef 750 mg, IV/IM, MHRA, UK.**	
	For generic drugs (me-too status)	Dowcef 750 mg IV/IM, Martin Dow.	
	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)	
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,	

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 750 mg IV/IM (GSK Pakistan) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterility and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri010-001	Tri010-002	Tri010-003
Batch Size	1000 vials	1000 vials	1000 vials

Manufacturing Date		09-2021	09-2021	09-2021
Date of Initiation		09-2021	09-2021	09-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted		

Remarks of Evaluator:

S.no.	Section	Description
1	**2.3.P.1**	Provide summarized information (including type of diluent, its composition, quantity or vol specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent w is to be provided along with the applied drug product.
2	**2.3.P.2.6**	Compatibility studies for the dry powder for injections and dry powder for suspension sha performed as per the instructions provided in individual label of the drug product.
3	**2.3.R.1.1**	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for w stability studies data is provided in Module 3 section 3.2.P.8.3
4	**3.2.S.4**	• Analytical Method Verification studies including specificity, accuracy and repeatal (method precision) performed by the Drug Product manufacturer for both compendial as as non-compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Pro manufacturer used during product development and stability studies, along with Certifica Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingre manufacture. • COA of primary / secondary reference standard including source and lot number sha provided.
5	**3.2.S.7**	• Significant change in accelerated stability studies of Drug substance manufacturer batc 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and µg/mg to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stal studies data
6	**3.2.P.3**	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been prov Justification required. Furthermore, in Standard manufacturing procure preparatio solution, filtration and filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Tax Justification shall be submitted.

		• The process validation protocols do not contain any steps to ensure the sterilization of and rubber stopper is adequately performed, further the time and temperature of steriliz cycle is also not validated. Justification is required in this regard.
7	**3.2.P.5**	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Te procedure use is UV spectrophotometer at wavelength of 245nm. However, In of monograph USP its method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use is spectrophotometer at wavelength of 245nm. However, In official monograph USP its me on HPLC. • Detailed analytical procedures used for testing the drug product shall be provided.
8	**3.2.P.7**	Please provide detail of the container closure systems, description of the primary container clo systems, including materials of construction, unit count or fill size, container size or volume be provided. Please also provide USP type of glass vials.
9	**3.2.P.8**	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotom method. However, in stability studies HPLC chromatograms are provided, which are n accordance with USP official monograph. As in USP monograph Orcinol in water conta 1.5 mg per mL has been used as internal standard and the resolution, *R*, between the an and internal standard peaks is not less than 3.5. However, in provided chromatograms the no peak of Orcinol. Justification required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability cham (real time and accelerated) shall be submitted. • Please provide Certificate of analysis of API which is actually used in manufacturin product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product te for each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regul authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Summary of additional stability studies (if applicable) e.g. in-use studies for drug pro which are to be reconstituted before use, along with proposed in-use storage statement an use shelf-life shall be provided.

Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

973.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 21166 dated 27-07-2022	
	Details of fee submitted	**PKR 30,000/-**	**dated 30-04-2022(72888767)**

	The proposed proprietary name / brand name	Roxime Injection 1.5 g IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 1.5 g
	Pharmaceutical form of applied drug	vial IV/IM
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	1X10ml
	Proposed unit price	As per rule
	The status in reference regulatory authorities	**Zinacef 1.5 g, IV/IM, MHRA, UK.**
	For generic drugs (me-too status)	Dowcef 1.5g IV/IM, Martin Dow.
	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 1.5g IV/IM (GSK Pakistan) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterility and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri009-001	Tri009-002	Tri009-003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Description
1	**1.5.4**	Justification shall be provided for pack size of 1.5 g IM/IV injection (10 ml). However, as per innovator its dilution is required with 15 ml water for injection.
2	**2.3.P.1**	Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product.
3	**2.3.P.2.6**	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.
4	**2.3.R.1.1**	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
5	**3.2.S.4**	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • COA of primary / secondary reference standard including source and lot number shall be provided.
6	**3.2.S.7**	• Significant change in accelerated stability studies of Drug substance manufacturer batch no 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and 848 µg/mg to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stability studies data
7	**3.2.P.3**	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been provided. Justification required. Furthermore, in Standard manufacturing procure preparation of solution, filtration and filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Taxime. Justification shall be submitted. • The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.
8	**3.2.P.5**	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Testing procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Detailed analytical procedures used for testing the drug product shall be provided.
9	**3.2.P.7**	Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials.
10	**3.2.P.8**	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotometer method. However, in stability studies HPLC chromatograms are provided, which are not in accordance with USP official monograph. As in USP monograph Orcinol in water containing 1.5 mg per mL has been used as internal standard and the resolution, *R*, between the analyte and internal standard peaks is not less than 3.5. However, in provided chromatograms there is no peak of Orcinol. Justification required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.

		• Please provide Certificate of analysis of API which is actually used in manufacturing of product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Decision: Registration Board aceeded to the request of M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512) for withdrawal of their above mentioned applications and declared them as disposed off.

PREVIOUSLY DEFERRED CASES OF FORM-5

974.	Name and address of manufacturer / Applicant	M/s Wnsfield Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Orliwin 120mg capsule
	Diary No. Date of R& I & fee	Each capsule contains: Orlistat (50.0% pellets)……..120mg
	Composition	Dy. No.1522; 28-03-2017; Rs.20,000/- (27-03-2017)
	Pharmacological Group	Lipase Inhibitor
	Type of Form	Form 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Orlis 120mg capsule of M/s Ferozsons
	GMP status	DML Renewal Inspection Date: 18th January, 2018
	Previous remarks of the Evaluator.	Source of pellets is not provided by the firm.
	Previous decision(s)	●Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. (M-279)
	Evaluation by PEC	●The firm has submitted Source of pellets: M/s Vision Pharmaceuticals COA of Orlistat IR Pellets 50.0% Stability study datasheet of 3 batches certificate granted based on inspection conducted on 26-01-2018.
	Decision of 282nd meeting of Registration Board	**Deferred for further deliberation upon requirement of accelerated stability study data of Orlistat pellets**
	Response of the Firm	Firm replied that "Our product Orlistat 120mg Capsule was deferred in DRB 282 Meeting due to further deliberation upon requirement of accelerated stability study data of Oristat pellets".In this regard we're submitting the Stability Data Sheets Along with DML, and COA of Orlistat Pellets by M/s Alphamed Formulations Private Limited India."We would further bring into your notice that this is the same source from where the registration holder companies of Orlistat Capsule in Pakistan, are already importing Orlistat Pellets. For reference we have attached the image of Import Data"

		However, previously firm claimed that their source of pellets is M/s. Vision Pharmaceuticals, Now they are submitting DML, COA and stability data performed at real time condition of Orlistat Pellets by M/s Alphamed Formulations Private Limited India., while the point of discussion is relevant to **accelerated stability study data of Orlistat pellets.**
	Decision: Deferred for submission of stability study data of Orlistat pellets performed at accelerated conditions.	
975.	Name and address of manufacturer / Applicant	M/S Lisko Pakistan (Pvt) Ltd. L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Telsart HCT 80mg/25mg Tablet
	Composition	Each tablet contains: Telmisartan USP …….80mg Hydrochlorothiazid……..25mg
	Diary No. Date of R& I & fee	Dy.No.13655; 28-08-2017; Rs.20,000/- (25-08-2017)
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status (with strength and dosage form)	Teli-H Tabletsof M/S Wilson's Pharmaceuticals
	GMP status	Last GMP inspection is conducted on 24-4-2018 & report concludes that overall firm has satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Evidence of double compression machine not found.
	Decision of 283rd meeting of Registration Board	Registration board deferred the case for Evidence of double compression Machine verified by FID. Moreover, Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies.
	Response of the Firm	Firm submitted certificate of availability of more than two functional stability chamber and the certificate is attested by the area FID. Further firm submitted the copy of routine GMP inspection reprt dated 15th February,2024 in which it was noted that firm has Bi-Layered tablets compression and Co-blistering facility in all section including general tablets,penicillin section and Cephalosporin section.
	Decision: Approved.	
976.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Telsart Plus Tablet 40/12.5mg
	Composition	Each tablet contains: Telmisartan...40mg Hydrochlorothiazide…....12.5mg
	Diary No. Date of R& I & fee	Dy. No. 13671, 28-08-2017, Rs. 20,000/- 25-08-2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's & 28's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of Uk

	Me-too status	Velmon-H 40/12.5mg Tablet of M/s Martin Dow Ltd. Karachi (Reg.#081160)
	GMP status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision of 283rd meeting of Registration Board	Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies.
	Response of the Firm	Firm submitted certificate of availability of more than two functional stability chamber and the certificate is attested by the area FID. Further firm submitted the copy of routine GMP inspection reprt dated 15th February,2024 in which it was noted that firm has Bi-Layered tablets compression and Co-blistering facility in all section including general tablets,penicillin section and Cephalosporin section.
	Decision: Approved.	
977.	Name and address of manufacturer / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Lemex Injection 150mg
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. 2284 dated 16/06/2011 Rs. 8,000/- (Photocopy fee challan) Dy. No. dated 16/12/2015 Rs. 12,000/- (Photocopy fee challan) (Receipt of application verified by R&I)
	Composition	Each ml contains: - Clindamycin ……. 150mg
	Pharmacological Group	Lincosamide (Antibiotic)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	4 x 1ml's
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Cleocin Injection by Mediceena Pharma (Clindamycin Phosphate) (Reg No. 028815)
	GMP Status	Panel inspection for renewal of DML conducted on 15-12-2020,16-12-2020,26-01-2021 concluded with the following remarks: "The panel recommends the renewal of Drug Manufacturing License to M/s. Jawa Pharmaceuticals (Pvt.) Ltd., Lahore by way of formulation"
	Remarks of the Evaluator.	Approval status of applied formulation could not be confirmed in Reference Regulatory Agencies.
	Decision of 308th meeting of Registration Board	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.
	Response of the Firm	Firm submitted the evidence of approval of applied product in MHRA, but the reference product is clindamycin phosphate with the pack size of 2ml,4ml &6ml ,while the applied product clindamycin base and demanded pack size was 1ml.
	Decision: Approved with following label claim; **Each ml contains: -** **Clindamycin Phosphate ……. 150mg** **Registration letter will be issued after Submission of differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug**	

	substance), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021 shall be submitted.	
978.	Name and address of manufacturer / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Jawaflox Dry Suspension
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No.5265 dated 11/05/2011 Rs. 8,000/- (Photocopy fee challan) Dy. No. dated 16/12/2015 Rs. 12,000/- (Photocopy fee challan) (Receipt of application verified by R&I)
	Composition	Each 5ml contains: - Ciprofloxacin HCl ……. 250mg
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60 ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ciproxin 250mg/5ml granules and solvent for oral suspension by Bayer (MHRA Approved)
	Me-too Status	Novidat Dry Powder for Suspension by Sami Pharma
	GMP Status	Panel inspection for renewal of DML conducted on 15-12-2020,16-12-2020,26-01-2021 concluded with the following remarks: "The panel recommends the renewal of Drug Manufacturing License to M/s. Jawa Pharmaceuticals (Pvt.) Ltd., Lahore by way of formulation"
	Remarks of the Evaluator.	• Justify the formulation containing ciprofloxacin as hydrochloride since the reference formulation approved by MHRA contains ciprofloxacin base. • Provide source of granules of ciprofloxacin since granulation process is not mentioned in method of manufacturing.
	Decision of 308th meeting of Registration Board	Deferred for the Revision of formulation as the reference formulation by MHRA contains Ciprofloxacin base, while the applied formulation contains ciprofloxacin as hydrochloride. Accordingly, firm has to submit the revised Form-5, master formulation and manufacturing method along with requisite fee.
	Response of the Firm	Firm again submitted the master formulation and label claim of formulation containing ciprofloxacin hydrochloride along with fee of Rs.7500/-
	Decision: Approved	
979.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	JASTINE SYRUP (Ebastine 5mg/5ml)
	Composition	Each 5ml contains: Ebastine…...5mg
	Diary No. Date of R & I & fee	Dy. No. 274 dated 24-03-2009, Rs. 8,000/- dated Challan (not provided) Dy. No. 267 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0523895 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I cover letter copy of initial submission not provided Verification of initial and differential fee submissions along with challans required)
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebastel oral solution 1mg/ml of Almirall, (AEMPS – CIMA Spain Approved)
	Me-too status	Fystine Liquid Syrup of M/s Fynk Pharmaceuticals, Lahore. (Reg. # 077173)
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • Provide DRAP R & I stamped cover letter of initial submission of application form along with fee challan. • Product is non-pharmacopoeia and firm has claimed manufacturer specifications. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision of 321st meeting of Registration Board	Deferred for following: Verification of DRAP R & I record of initial submission of registration application along with fee.
	Response of the Firm	Firm submitted a copy of covering letter of initial submission of registration application stamped with R&I receiving along with copy of fee challan of Rs.8,000/-.
	Decision: Approved. Fee shall be verified as per the decision taken by the Registration Board in its 285th meeting.	
980.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma, Plot No 2610. Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Esglit tablet 5mg
	Composition	Each film- coated tablet contains: Escitalopram Oxalate Eq. to Escitalopram….....5mg
	Diary No. Date of R & I & fee	Dy.No.2090 dated 16-01-2019 Rs.20,000/- Dated 17-01-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 50's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Rize- plus tablet 5 mg of M/s Werrick Pharmaceuticals Islamabad (Reg.# 068875)
	GMP status	The firm was inspected on 16.01.2019. The panel recommended the grant of GMP certificate.
	Remarks of the EvaluatorXIII	• Methylene chloride has been used in the applied coating solution. • Firm has general tablet section as mentioned in the submitted GMP inspection report.
	Decision of 296th meeting of Registration Board	Deferred as a banned excipient Methylene chloride has been used in the applied coating solution.
	Response of the Firm	Firm submitted a revised formulation of applied product excluding methylene chloride without requisite fee.
	Decision: Approved **Registration letter will be issued after Submission of differential fee of Rs. 7500/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021 shall be submitted**	

Agenda of Evaluator PEC-XX

Priority consideration on account of Export Facilitation:

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements
Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 02.06.2023:

981.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 03.08.2022 based on inspection dated May 16,17,20,23 and 24, 2022 valid for 2 years from the date of issue
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for Regularization of existing facility dated 22-06-2018 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9816 (R&I) DRAP, dated 12/04/2023
	Details of fee submitted	PKR 75,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	Bemdo-Ez 180/10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Bemedoic acid ……..….180mg Ezetimibe……10mg
	Pharmacotherapeutic Group of (API)	Lipid modifying agent
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nustendi 180/10mg tablet MHRA Approved
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Bempedoic Acid: Metrochem API Pvt. Ltd. Unit IV, Plot No 34B, 40B & 60B, J.N Pharma, City , Thanam (V), Prawada (M), Visakhapatnam, Dist-531021, Andhra Pradesh, India Ezetimibe USP:

		Ind-Swift Laboratories Ltd, village Bhagwanpur, Barwala Road, Derabassi, District S.A.S. Nagar Punjab.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Bempedoic acid: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 12 months. Batches: HAN-P/21003 HAN-P/21004 HAN-P/21005 Ezetimibe : Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months. Batches: 1366020002 1366020003 1366020004
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Nexlizet tablet (Batch No 1855166) by M/s Esperion Therapeutics Inc (Exp date 11/2022) Quality parameters such as appearance, average weight, DT dissolution, assay, uniformity of dosage unit, microbial limit and impurity were compared. CDP has been performed against the same brand that is Nexlizet tablet (Batch No 1855166) by M/s Esperion Therapeutics Inc (Exp date 11/2022) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Bempedoic Acid: Metrochem API Pvt. Ltd. Unit IV, Plot No 34B, 40B & 60B, J.N Pharma, City , Thanam (V), Prawada (M), Visakhapatnam, Dist-531021, Andhra Pradesh, India Ezetimibe USP: Ind-Swift Laboratories Ltd, village Bhagwanpur, Barwala Road, Derabassi, District S.A.S. Nagar Punjab.		
API Lot No.	Bempedoic Acid: HAN-PM/22003 Ezetimibe: L385039002		
Description of Pack (Container closure system)	Alu-Alu blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	12-08-2022	12-08-2022	12-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Bempedoic acid: Firm has submitted copy of GMP Certificate E-1862189/DD/DCA/VSP/2022 issued by Govt. of Andhra Pradesh Drug control administration dated 14-11-2022. Valid till 1 year from the date of issue. Ezetimibe USP: Firm has submitted copy of GMP Certificate No. Drugs (1) Pb./2022/13143 issued by Food & Drugs Administration Punjab dated 06-12-2022. Valid till 2 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Bempedoic acid: Provided copy of commercial invoice (Invoice# DE/22-23/0031 dated 30th April 2022, with received quantity i.e. 3Kg) for the purchase of Bempedoic acid from Metrochem API Pvt Ltd and License from DRAP dated 16/05/2022 (batch no. HAN-PM/22003) Ezetimibe USP: Provided copy of commercial invoice (Invoice# 9100019689 dated 29th Feb 2020, with received quantity i.e. 20Kg) for the purchase of Ezetimibe USP from Ind-Swift Laboratories Ltd, buyer name mentioned as Hilton Pharma, Karachi (loan agreement provided) (batch no. L385039002)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	3.2.P.5.1& 3.2.P.8 The finished product release specifications include tests for appearance, dimensions, identity (HPLC), assay (HPLC), impurities (HPLC) dissolution (HPLC), uniformity of dosage units (ph. eur.), water content (kf), microbial limits (ph. eur.) https://www.ema.europa.eu/en/documents/assessment-report/nustendi-epar-public-assessment-report_en.pdf However, water content (KF) not performed under finished product specification and stability data	Initially we have found the FDA Chemistry Report of Nexlizet (bempedoic acid and ezetimibe) 180 mg/10mg tablets which does not mention the water content test. On query we searched and found the EMA Assessment Report on Nustendi (bempedoic acid and ezetimibe) 180 mg/10mg, mentioning the water content test.	Water content test has been included under finished product specification Moreover performance /results are provided.

		We have performed the water content test on our product on same lab scale batches after 18months at long term stability conditions i.e. 30°C/75%. Results are given below:	
2.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
3.	3.2.S.5 COA of primary / secondary reference standard including source and lot number to be provided	Provided	Complied
4.	3.2.P.8 Documents for the procurement of both API attested by DRAP to be provided.	Commercial invoices and license to import API have been provided	Clearance certificate of both API from DRAP yet to be provided

Water content test results.

Product Name	Batch Number	Water content %
Bempedoic Acid 180mg+ Ezetimibe 10mg Tablet (SAMI product)	Lab-01	3.22%
	Lab-02	3.51%
	Lab-03	3.27%
Nexlizet (bempedoic acid and ezetimibe) 180 mg/10mg tablets. (Innovator product)	1855166	3.10%

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

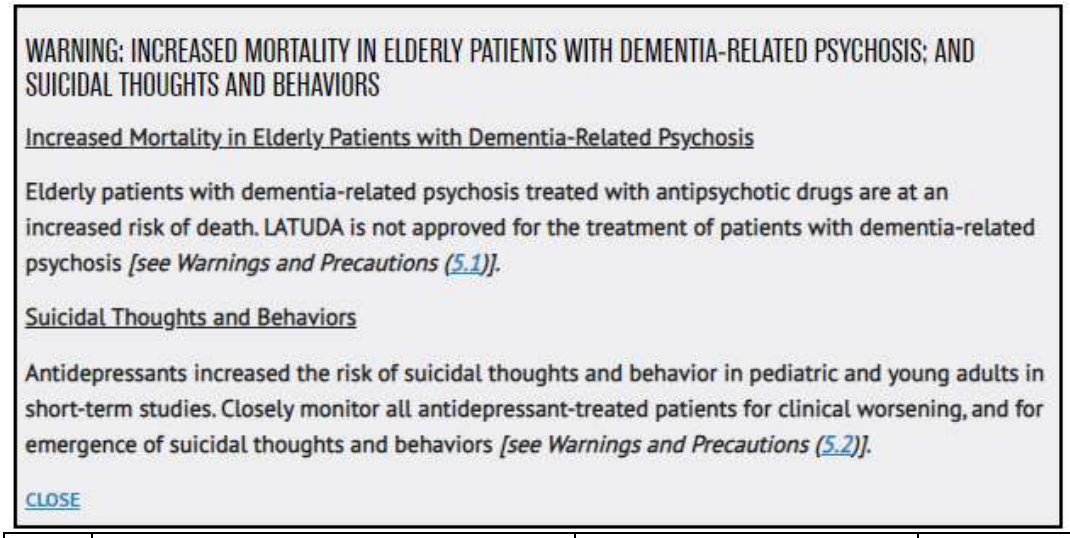
Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 06.10.2022:

982.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate dated 07.10.2021 based on inspection dated 15.06.2021 valid for two years.

	Evidence of approval of manufacturing facility	Tablet General section has been approved by CLB in 282nd meeting and letter issued dated 30.09.2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 59 dated 12.10.2015 Form 5D Dy. No. 17837 dated 20/06/2022 (stability data submission)
	Details of fee submitted	PKR 50,000/-: dated 20/01/2015
	The proposed proprietary name / brand name	Lura Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Lurasidone HCl……....20mg
	Pharmacotherapeutic Group of (API)	To treat Schizophrenia and Bipolar disorder
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Not provided
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	Rs 2118/ tab Rs 21180/10's Rs 42360/20's Rs 63540/30's
	The status in reference regulatory authorities	USFDA approved Latuda 20mg tablet
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Solara Active Pharma Sciences Ltd R.S.No 33 &34 Mathur road, Periyakalapet, Puducherry, India

STABILITY STUDY DATA			
Manufacturer of API	Solara Active Pharma Sciences Ltd R.S.No 33 &34 Mathur road, Periyakalapet, Puducherry, India		
API Lot No.	PLHP200001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	20SB(A)-040-01	20SB(A)-041-02	20SB(A)-042-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	25-01-2021	25-01-2021	25-01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API (batch No PLHP200001)is provided from both API Manufacturer and Finished Product manufacturer
3	Method used for analysis of API from both API Manufacturer & Finished Product manufacturer	Provided
4	Stability study data of API from API manufacturer	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B# 3LHC041602, B#3LHC041603, B# 3LHC041604
5	Protocols followed for conduction of stability study	Provided
6	Method used for analysis of FPP	Not provided
7	Drug-excipients compatibility studies (where applicable)	Not applicable
8	Complete batch manufacturing record of three stability batches	Provided
9	Record of comparative dissolution data	Not provided
10.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No 1690/DDC/Solara/WHO-GMP/U-II/2021-2022/1074 dated 03.02.2022 in the name of Solara Active Pharma Sciences Ltd valid till 03.12.2024.
11.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No 1105300028 dated 01.02.2020 wherein quantity of Lurasidone HCl was mentioned as 2Kg Batch No PLHP200001. Cleared by DRAP I&E Karachi dated 18.02.2020
12.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets for 2 batches
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Complied
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Complied .
Remarks of Assessor (DD PEC XX): Box warning by USFDA for approved product as follows:		



WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LATUDA is not approved for the treatment of patients with dementia-related psychosis *[see Warnings and Precautions (5.1)]*.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adults in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions (5.2)]*.

CLOSE

S.No	Observations	Reply	Remarks
1.	Analytical method validation studies of Drug Substance by Drug product manufacturer to be provided	Provided	Complied
2.	Provide stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets of Batch 20SB(A)-042-03.	Provided	Complied
3.	Provide method used for analysis of FPP along with validation studies.	Provided	Complied
4.	Provide pharmaceutical equivalence /comparative dissolution profile against reference product.	Pharmaceutical equivalence has been performed against LATUDA 20mg tablet (Batch No C5169) by Sunovion. Quality parameters compared were identification, dissolution, assay DT	CDP profile yet to be provided. *Firm has provided CDP report against LATUDA 20mg tablet (Batch No C5169)*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 02.06.2023:

983.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has provided GMP certificate dated 03.08.2022 based on inspection dated May 16,17,20,23 and 24, 2022 valid for 2 years from the date of issue
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for Regularization of existing facility dated 22-06-2018 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10009 (R&I) DRAP, dated 13/04/2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	VIEJA ER 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release film coated tablet contains: Mirabegron ……..……..….50mg
	Pharmacotherapeutic Group of (API)	Beta 3 adrenergic agonist (Drug for urinary frequency and incontinence)
	Pharmaceutical form of applied drug	Extended release Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Betamiga 50mg PR tablet EMA Approved
	For generic drugs (me-too status)	Mibega tablet by Getz (Reg No 089378)
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Jiangxi Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20180101V, 20180102V, 20180103V)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Mibega 50mg tablet (Batch No 024FB8) by M/s Getz Pharmaceutical (Exp date 09/2023) Quality parameters such as appearance, average weight, dissolution, assay, uniformity of dosage unit, microbial limit and impurity were compared. CDP has been performed against the same brand that is Mibega 50mg tablet (Batch No 024FB8) by M/s Getz Pharmaceutical (Exp date 09/2023) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Jiangxi Province China.		
API Lot No.	20200603V		
Description of Pack (Container closure system)	Alu-Alu blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 ,9,12 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	Lab-06	Lab-05	Lab-04
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	Sep 2021	Sep 2021	Sep 2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate dated 12/03/2020 issued by Jiangxi API Engineering Technology Research Center valid till 11th March 2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# JXS210448 dated 13th April 2021, with received quantity i.e. 2Kg) for the purchase of Mirabegron from Jiangxi Synergy Pharmaceutical Co., Ltd and clearance certificate from DRAP dated 21/04/2021 (batch no. 20200603V)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
	3.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Polyethylene oxide and Silicon dioxide fumed) to be provided since said excipients are not found in innovator/reference product	Compatibility studies were performed against said excipients by performing stress studies. No degradation and peak interference with principal peak was observed	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 02.06.2023:

984.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 03.08.2022 based on inspection dated May 16,17,20,23 and 24, 2022 valid for 2 years from the date of issue
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for Regularization of existing facility dated 22-06-2018 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10009 (R&I) DRAP, dated 13/04/2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	VIEJA ER 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release film coated tablet contains: Mirabegron ……..……..….50mg
	Pharmacotherapeutic Group of (API)	Beta 3 adrenergic agonist (Drug for urinary frequency and incontinence)
	Pharmaceutical form of applied drug	Extended release Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Betamiga 50mg PR tablet EMA Approved
	For generic drugs (me-too status)	Mibega tablet by Getz (Reg No 089378)
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Jiangxi Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20180101V, 20180102V, 20180103V)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Mibega 50mg tablet (Batch No 024FB8) by M/s Getz Pharmaceutical (Exp date 09/2023) Quality parameters such as appearance, average weight, dissolution, assay, uniformity of dosage unit, microbial limit and impurity were compared. CDP has been performed against the same brand that is Mibega 50mg tablet (Batch No 024FB8) by M/s Getz Pharmaceutical (Exp date 09/2023) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Jiangxi Province China.		
API Lot No.	20200603V		
Description of Pack (Container closure system)	Alu-Alu blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 ,9,12 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	Lab-06	Lab-05	Lab-04
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	Sep 2021	Sep 2021	Sep 2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate dated 12/03/2020 issued by Jiangxi API Engineering Technology Research Center valid till 11th March 2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# JXS210448 dated 13th April 2021, with received quantity i.e. 2Kg) for the purchase of Mirabegron from Jiangxi Synergy Pharmaceutical Co., Ltd and clearance certificate from DRAP dated 21/04/2021 (batch no. 20200603V)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
	3.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Polyethylene oxide and Silicon dioxide fumed) to be provided since said excipients are not found in innovator/reference product	Compatibility studies were performed against said excipients by performing stress studies. No degradation and peak interference with principal peak was observed	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 02.06.2023:

985.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 30.8.2019 based on inspection dated 28.08.2019 valid for 1 year from the date of issue
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for Regularization of existing facility dated 22-06-2018 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35846 (R&I) DRAP, dated 09/12/2022
	Details of fee submitted	PKR 75,000/- Dated 22-06-2022
	The proposed proprietary name / brand name	Trela 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Trelagliptin Succinate eq to Trelagliptin ……..……..….100mg
	Pharmacotherapeutic Group of (API)	Antidiabetic (Dipeptidyl peptidase 4 inhibitor)
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 10's, 14's and 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	OWT Tablet 100mg by PharmEvo Karachi (Reg No 117985)
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co Ltd No 21 Huancheng West Road Anqing Anhui China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20180606, 20180613, 20180620)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Zafatek 100mg tablet (Batch No 522026) by M/s Takeda Pharmaceutical (Exp date 05/2025) Quality parameters such as appearance, average weight, hardness dissolution, DT, assay, microbial limit and impurity were compared. CDP has been performed against the same brand that is Zafatek 100mg tablet (Batch No 522026) by M/s Takeda Pharmaceutical in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The % drug release in all three mediums is more than 85% in 15 min hence f2 value is not calculated.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Anhui Haikang Pharmaceutical Co Ltd No 21 Huancheng West Road Anqing Anhui China		
API Lot No.	21072401		
Description of Pack (Container closure system)	Alu-PVC packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	06-01-2022	06-01-2022	06-01-2022

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate dated 09/09/2019 issued by Anqing Biomedical Industry Association valid till 09th September 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# WD202105041 dated 27th July 2021, with received quantity i.e. 2Kg) for the purchase of Trelagliptin Succinate from Anhui Haikang Pharmaceutical Co. Ltd China and clearance certificate from DRAP dated 12/08/2021 (batch no. 21072401)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
	Provide updated GMP status of finished product manufacturer	Firm has provided GMP certificate dated 03.08.2022 based on inspection dated May 16, 17,20,23 and 24, 2022 valid for 2 years from the date of issue	Complied
	3.2.P.8 Provide Stability data including summary data sheet, chromatograms , CoA and raw data sheets (both accelerated and real time) for 6th month period (for batch No Lab-01) Moreover 3rd month data is required for Batch No Lab-02 and 6th month data is required for Batch No Lab-03	Provided	Complied
	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 13.09.2023:

986.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No 44, Kahuta Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No 44, Kahuta Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate based on inspection dated 29.12.2020 valid for 2 years
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 20-06-2008 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7164 (R&I) DRAP, dated 13/03/2023
	Details of fee submitted	PKR 30,000/- Dated 28-02-2023
	The proposed proprietary name / brand name	Vocus 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……..……..….10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1 x 10's, 2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	Voniza Tablet 10mg Hilton pharma Reg No 108573
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co. Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20190801BD, 20190802BD, 20190803BD)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Takecab 10mg tablet by M/s Takeda Pharmaceutical Quality parameters such as identification, dissolution, DT and assay etc were compared. CDP has been performed against the same brand that is Takecab 10mg tablet by M/s Takeda Pharmaceutical in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd China
API Lot No.	102-20220202BD
Description of Pack (Container closure system)	Alu-Alu Blister packaging
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 3 months Accelerated: 3 months

Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	22KT01	22KT02	22KT03
Batch Size	3000 tab	3000 tab	3000 tab
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	21-10-2022	21-10-2022	21-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 2021003 dated 08/12/2021 issued by Jiangxi API Engineering Technology Research Center valid till 07th December 2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# JXSG220553 dated 10th June 2022, with received quantity i.e. 0.50Kg) for the purchase of Vonoprazan fumarate from Jiangxi Synergy Pharmaceutical Co. Ltd China and clearance certificate from DRAP dated 07/07/2022 (batch no. 102-20220202BD)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer	Firm has provided GMP certificate based on inspection dated 12.05.2023 valid for 2 years	Complied
	3.2.S.7 Provide Real time stability data of API up to shelf life since already provided data was for 6 months only	Real time stability data has been provided for 36 months of following 3 batches: Batches: 20190801BD 20190802BD 20190803BD	Complied
	3.2.P.2.2.1 Provide details of Innovator Pack against which pharmaceutical equivalence study/CDP was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Pharmaceutical equivalence was determined against Takecab 10mg tablet by	Complied

		M/s Takeda Pharmaceutical Batch No: 475776 Exp date: 04-2023	
	3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) while dissolution medium used by the firm is Phosphate buffer (pH 6.8). .Justification to be provided for selection of dissolution medium.	We believe that this selection provides a more accurate representation of the in vivo conditions under which the Drug is intended to act.	Vonoprazan act in gastric environment where it inhibit H+-K+ ATPase enzyme system in a Potassium competitive manner. Hence firm's stance need to be justified
	3.2.P.8 Provide Stability data particularly chromatograms , CoA and raw data sheets (both accelerated and real time) for 6th month and onward time points	Provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 13.09.2023:

987.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No 44, Kahuta Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No 44, Kahuta Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate based on inspection dated 29.12.2020 valid for 2 years
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 20-06-2008 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15011 (R&I) DRAP, dated 14/06/2023
	Details of fee submitted	PKR 30,000/- Dated 15-03-2023
	The proposed proprietary name / brand name	Vocus 20mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……..……..….20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1 x 10's, 2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	Voniza Tablet 20mg Hilton pharma Reg No 108572
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co. Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20190801BD, 20190802BD, 20190803BD)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Takecab 20mg tablet by M/s Takeda Pharmaceutical Quality parameters such as

		identification, dissolution, DT and assay etc were compared. CDP has been performed against the same brand that is Takecab 20mg tablet by M/s Takeda Pharmaceutical in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd China		
API Lot No.	102-20220202BD		
Description of Pack (Container closure system)	Alu-Alu Blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	22KT04	22KT05	22KT06
Batch Size	3000 tab	3000 tab	3000 tab
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	21-10-2022	21-10-2022	21-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 2021003 dated 08/12/2021 issued by Jiangxi API Engineering Technology Research Center valid till 07th December 2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# JXSG220553 dated 10th June 2022, with received quantity i.e. 0.50Kg) for the purchase of Vonoprazan fumarate from Jiangxi Synergy Pharmaceutical Co. Ltd China and clearance certificate from DRAP dated 07/07/2022 (batch no. 102-20220202BD)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer	Firm has provided GMP certificate based on inspection dated 12.05.2023 valid for 2 years	Complied
	3.2.S.7 Provide Real time stability data of API up to shelf life since already provided data was for 6 months only	Real time stability data has been provided for 36 months of following 3 batches: Batches: 20190801BD 20190802BD 20190803BD	Complied
	3.2.P.2.2.1 Provide details of Innovator Pack against which pharmaceutical equivalence study/CDP was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Pharmaceutical equivalence was determined against Takecab 20mg tablet by M/s Takeda Pharmaceutical Batch No: 474338 Exp date: 02-2023	Complied
	3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) while dissolution medium used by the firm is Phosphate buffer (pH 6.8). .Justification to be provided for selection of dissolution medium.	We believe that this selection provides a more accurate representation of the in vivo conditions under which the Drug is intended to act.	Vonoprazan act in gastric environment where it inhibit H+-K+ ATPase enzyme system in a Potassium competitive manner. Hence firm's stance need to be justified
	3.2.P.8 Provide Stability data particularly chromatograms , CoA and raw data sheets (both accelerated and real time) for 6th month and onward time points	Provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

988.	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report for grant of DML to be provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 29-04-2022 specifying Dry Powder suspension section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11135 (R&I) DRAP, dated 04/05/2023
	Details of fee submitted	PKR 30,000/- Dated 02-05-2023
	The proposed proprietary name / brand name	Maycil 250mg/5ml DS oral suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml constituted suspension contains: Clarithromycin……..….250mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, macrolide
	Pharmaceutical form of applied drug	Solution for injection (wrongly mentioned)
	Reference to Finished product specifications	USP
	Proposed Pack size	15ml, 30ml, 60ml and 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Klaricid 250mg/5ml oral suspension by M/s Abbott pharma Reg No 076148
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial triangle , Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: CTM0511, CTM0510, CTM0513
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Klaricid 250mg/5ml DS product by M/s Abbott Laboratories, Pakistan. (Batch No (17) 462786XV) Quality parameters such as Description, identification, Ph,, average weight, LOD, volume of reconstitution, color of reconstitution and assay were compared against Test product (Batch No T 01)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API (taste masked micro pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial triangle , Kahuta road, Islamabad		
API Lot No.	CTM0644		
Description of Pack (Container closure system)	Amber color plastic bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1	T2	T3
Batch Size	1000 Bottles	1000 Bottles	1000 Bottles
Manufacturing Date	22-05-2022	22-05-2022	22-05-2022
Date of Initiation	23-05-2022	24-05-2022	25-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No F.3-26/2019-Addl.Dir (QA&LT-I)-56 dated 22.08.2022 based on inspection dated 14.06.2022 valid till 13.06.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable However, firm has submitted invoice No 60007 dated 18.05.2022 wherein 30Kg clarithromycin taste Masked micro pellets 27.5% (Batch No CTM0644) was purchased
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Assessor (PEC-XX):

Sr.#	Observations	Reply/ Updated status	Remarks
1	3.2.P.8 In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	Firm has provided chromatograms only for in use stability study	In use stability data (reconstituted form) to be provided wherein all pharmacopoeial quality parameters will be tested and results should be shown in summary data sheet for each batch.
2	3.2.P.2 Provide Drug excipients compatibility study report for sodium citrate dehydrate, being qualitatively different from innovator product.	It is evidence from the stability studies that product is compatible with the excipients and Drug Product is stable throughout the stability studies.	Not Complied Drug excipients compatibility study report for sodium citrate dehydrate yet to be provided
3	3.2.P.2.2.1 Provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Provided	Complied
4	3.2.P.4 Deliverable volume testing has not been mentioned under finished product specification and stability study	Deliverable volume testing has been incorporated in stability testing	Complied

5	3.2.P.4 Results of specificity and accuracy has not been provided under analytical method verification study of Drug Product	Results of specificity (against standard, blank and placebo) and accuracy yet to be provided.	Not Complied
6	3.2.P.7 Provide details about container closure system (description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume)	Material of construction of plastic bottle yet to be provided	Not Complied
7	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Analytical Method used for analysis of API/pellets yet to be provided	Not Complied
8	3.2.S.4 Drug substance (micro pellets) manufacturer performed Dissolution testing as mentioned in analytical method/CoA while same has not been provided under CoA of clarithromycin granules from Drug product manufacturer.	Dissolution testing has been performed as provided in CoA of clarithromycin granules from Drug product manufacturer.	Complied
9	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied

Decision 330th meeting: Deferred for following::
Drug excipients compatibility study report for sodium citrate being qualitatively different from innovator product.
Results of specificity (against standard, blank and placebo) and accuracy to be provided under analytical method verification study of Drug Product
Method used for analysis of API from Finished Product Manufacturer to be provided
Provide details about container closure system (Material of construction of plastic bottle)
In use stability data (reconstituted form) of all pharmacopoeial quality parameters summarized in data sheet for each batch.

Reply:

Sr.#	Observations	Updated status	Remarks
1	Drug excipients compatibility study report for sodium citrate being qualitatively different from innovator product	It was typographic error Mono sodium citrate has been used in formulation instead of sodium citrate dehydrate and formulation is as per innovator	Complied Said ingredient Mono sodium citrate is found in MHRA approved product
2.	Results of specificity (against standard, blank and placebo) to be provided under analytical method verification study of Drug Product	Provided	Complied
3	Method used for analysis of API from Finished Product Manufacturer to be provided	Provided As per USP 43	Complied

4.	Details about container closure system (Material of construction of plastic bottle)	Amber colored PET Bottle	Complied
5	In use stability data (reconstituted form) of all pharmacopoeial quality parameters summarized in data sheet for each batch	In use stability data of two batches T1 and T2 for 0 and Day 7 has been provided	Complied
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			

Dry Powder Inhaler Capsule (General) section in place of Sachet (General)-New.

989.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35149 dated 05.12.2022
	Details of fee submitted	PKR 30,000/- dated 28.10.2022
	The proposed proprietary name / brand name	SBT Rota capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Salbutamol as Sulphate……200mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	β2 adrenergic agonist, bronchodilator
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ventolin Rotacap 200mcg TGA (Australia) approved
	For generic drugs (me-too status)	Breavent 200mcg capsule Highnoon Laboratories Reg. No. 044593
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for three years.

		New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D,F,C,N,O & unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(SS-0010613, SS-0010415 and SS-0010516)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Breavent 200mcg capsule by Highnoon Laboratories Batch No R102 by performing quality tests (Identification, Assay and standard weight against SBT Rota capsule
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.
STABILITY STUDY DATA		
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India	

API Lot No.	Not provided		
Description of Pack (Container closure system)	Not provided		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-55	T-56	T-57
Batch Size	500 Caps	500 Caps	500 Caps
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	03-01-2022	03-01-2022	03-01-2022
No. of Batches	03		
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)	
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided	

Remarks of Assessor (DD PECXX):

Label claim of RRA approved formulation (Ventolin 200 microgram, powder for inhalation, hard capsule) is as follows:

Each capsule contains 241 microgram salbutamol sulphate equivalent to 200 microgram salbutamol
Firm has not provided information regarding potency adjustment (salt form)

3.2.P.5 Applied formulation is available in BP monograph while specifications/ acceptance criteria of quality parameters tested (assay, uniformity of delivered dose, particle size distribution) were not as per BP monograph. Moreover, water content has not been determined as mentioned in BP.

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.P.2 In Pharmaceutical equivalence study identification and Assay was mentioned for Budesonide and Formoterol instead of salbutamol. Moreover, batch no of both Test product and Reference product to be provided.
3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.
3.2.P.2 Detailed Analytical method validation studies of Drug product is not provided
3.2.P.2 Detailed Analytical testing method of Drug Product to be provided.
3.2.P.2 Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /ROTAHALER (name, model, manufacturer, shelf life) provided in pack.
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision 326th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.

Reply:

Sr.#	Observation	Reply	Remarks
1.	Label claim of RRA approved formulation (Ventolin 200 microgram, powder for inhalation, hard capsule) is as follows: Each capsule contains 241 microgram salbutamol sulphate equivalent to 200 microgram salbutamol Firm has not provided information regarding potency adjustment (salt form)	Master formulation has been resubmitted wherein quantity of salt form (salbutamol sulphate) is mentioned as 241 microgram/capsule.	
2.	Applied formulation is available in BP monograph while specifications/ acceptance criteria of quality parameters tested (assay, uniformity of delivered dose, particle size distribution) were not as per BP monograph. Moreover, water content has not been determined as mentioned in BP.	Specification and analytical method of salbutamol sulphate as per BP has been submitted.	Results/ Performance report of critical quality attributes such as particle size distribution and aerodynamic assessment of particles is provided (as per BP) however, Results/

			Performance report of uniformity of delivered dose is still required.
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Analytical procedures for the testing of drug substance (as per BP) is provided by Drug product manufacturer	Complied
4.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	CoA of relevant batch (Batch No SS-0060721) is provided from both Drug Substance and Drug Product manufacturer	Complied
5.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Not provided	Results of Analytical method verification studies of Drug substance is still required from Drug product manufacturer.
6.	In Pharmaceutical equivalence study identification and Assay was mentioned for Budesonide and Formoterol instead of salbutamol. Moreover, batch no of both Test product and Reference product to be provided.	Not provided	Pharmaceutical equivalence study against Ventolin DPI (Batch No 52341) by GSK is provided including quality parameters such as standard weight, DT, Identification, content uniformity, content of delivered dose, assay.

7.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards	Batch formula for 1200 caps is provided included amount of all component used in formulation.	Complied
8.	Detailed Analytical method validation studies of Drug product is not provided	Not provided	Results of Analytical method validation study of Drug product is still required.
9.	Detailed Analytical testing method of Drug Product to be provided	Provided	Complied
10.	Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /ROTAHALER (name, model, manufacturer, shelf life) provided in pack.	Not provided	Not complied
11.	Documents for the procurement of API to be submitted.	Firm provided license to import drug issued by DRAP (dated 22.11.2021) wherein salbutamol sulphate (10g) has been mentioned moreover batch certification from API manufacturer is provided wherein salbutamol sulphate (Batch No SS-0060721) is mentioned	Clearance certificate from DRAP (I&E) is required.
12.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Record of Digital data logger for temperature and humidity monitoring is provided	

Finished product specification to be corrected as "BP" along with fee of Rs 7500/-
Also submit the registration status of previously registered products for "Sachet (general) section

Decision: Approved.

- **Before issuance of Registration letter, results of Analytical method validation study of Drug product to be provided. Moreover, finished product specification to be corrected as "BP" along with fee of Rs 7500/-**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Dry Powder Inhaler Capsule (General) section in place of Sachet (General)-New.

990.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,

	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35148 dated 05.12.2022
	Details of fee submitted	PKR 30,000/- dated 28.10.2022
	The proposed proprietary name / brand name	Tybro 18mcg Rota capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Tiotropium as Bromide Monohydrate……18 mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	Anticholinergic
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Spiriva 18mcg inhalation powder MHRA approved
	For generic drugs (me-too status)	Trovair 18mcg capsule Highnoon Laboratories Reg. No. 054315
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for three years. New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, and stability studies of

		drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,C,E,F,G&H & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(MDR-VI/001/11, MDR-VI/002/11and MDR-VI/003/11)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Trovair 18mcg capsule by Highnoon pharma, Batch No R102 by performing quality tests (Identification, Assay and standard weight against Tybro 18mcg Rota capsule
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.

STABILITY STUDY DATA			
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Not provided		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-43	T-44	T-45
Batch Size	500 Caps	500 Caps	500 Caps

Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		17-12-2021	17-12-2021	17-12-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)		
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided		

Remarks of Assessor (DD PECXX):

Label claim of RRA approved formulation (SPIRIVA 18 microgram, inhalation powder, hard capsule) is as follows:

Each capsule contains 22.5 microgram tiotropium bromide monohydrate equivalent to 18 microgram tiotropium.

The delivered dose (the dose that leaves the mouthpiece of device) is 10 microgram tiotropium.

Firm has not provided information regarding potency adjustment (salt form) and delivered dose.

The finished product specifications include acceptable tests and limits for appearance, identity (HPLC and ultra violet), assay, content uniformity, water content, degradation products, mean delivered dose, uniformity of delivered dose, aerodynamic particle size, foreign particulate matter, amorphous content and microbial purity.
https://www.tga.gov.au/sites/default/files/auspar-tiotropium-190613.pdf

while firm has mentioned finished product specifications including weight variation, identification, uniformity of delivered dose, particle size distribution, and Assay only. same have been tested during stability studies as well. Tests like content uniformity, water content, mean delivered dose, foreign particulate matter, amorphous content and microbial purity to be performed.

As per Public assessment report of Tiogiva 18mcg Inhalation Powder (MHRA approved) quality parameters such as dissolution testing, particle size distribution and delivered dose testing to be compared while firm has performed tests such as Identification, Assay and standard weight only

https://mhraproducts4853.blob.core.windows.net/docs/448c8da22b062d7f6226d1ed404ff80765b705aa

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by both Drug product and Drug Substance manufacturer

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards

3.2.P.2 Detailed Analytical method validation studies of Drug product is not provided

3.2.P.2 Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /Handihaler (name, model, manufacturer, shelf life) provided in pack.

3.2.P.8 Documents for the procurement of API to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision 326th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.

Reply of firm:

Sr .#	Observations	Reply	Remarks
1.	Label claim of RRA approved formulation (SPIRIVA 18 microgram, inhalation powder, hard capsule) is as follows: Each capsule contains 22.5 microgram tiotropium bromide monohydrate equivalent to 18 microgram tiotropium. The delivered dose (the dose that leaves the mouthpiece of device) is 10 microgram tiotropium. Firm has not provided information regarding potency adjustment (salt form) and delivered dose.	Master formulation has been resubmitted wherein quantity of salt form (tiotropium bromide monohydrate) is mentioned as 22.5 microgram/capsule.	Delivered dose (that leaves the mouthpiece of device) has been mentioned as 9.5 microgram/inhalation while innovator product claimed it to be 10ug/inhalation
2.	The finished product specifications include acceptable tests and limits for appearance, identity (HPLC and ultra violet), assay, content uniformity, water content, degradation products, mean delivered dose, uniformity of delivered dose, aerodynamic	Instead of providing updated finished product	Finished product specifications are resubmitted

	particle size, foreign particulate matter, amorphous content and microbial purity. https://www.tga.gov.au/sites/default/files/auspar-tiotropium-190613.pdf while firm has mentioned finished product specifications including weight variation, identification, uniformity of delivered dose, particle size distribution, and Assay only. same have been tested during stability studies as well. Tests like content uniformity, water content, foreign particulate matter, aerodynamic particle size, amorphous content and microbial purity to be performed.	specifications firm provided specifications of API.	Wherein tests like content uniformity, water content, content of delivered dose and content uniformity have been mentioned. Performance report of quality tests such as aerodynamic assessment of particles and uniformity of delivered dose has been provided.
3.	As per Public assessment report of Tiogiva 18mcg Inhalation Powder (MHRA approved) quality parameters such as dissolution testing, particle size distribution and delivered dose testing to be compared while firm has performed tests such as Identification, Assay and standard weight only https://mhraproducts4853.blob.core.windows.net/docs/448c8da22b062d7f6226d1ed404ff80765b705aa	Not provided	Pharmaceutical equivalence study report against Tiovair by Highnoon Laboratories (Batch No 221101) is provided containing test results for dissolution testing, particle size distribution and content of delivered dose.
4.	Detailed analytical procedures for the testing of drug substance to be provided by both Drug product and Drug Substance manufacturer	Provided (as per Euorpean pharmacopeia)	Complied
5.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	CoA of batch (Batch No TBM-0190821) is provided from both Drug Substance and Drug Product manufacturer	Complied

6.	Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /Handihaler (name, model, manufacturer, shelf life) provided in pack.	Aluminium foil 10caps/blister Inhalation device name: WRLflo Manufacturer: Winbrain Model: WRL-00824	
7.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Complied
8.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards	Provided	Complied
9.	Documents for the procurement of API to be submitted.	Firm provided license to import drug issued by DRAP (dated 22.11.2021) wherein tiotropium bromide monohydrate (10g) has been mentioned	Clearance certificate from DRAP (I&E) is required. Moreover, batch no of API need to be mentioned.
10.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards	Batch formula for 1200 caps is provided included amount of all component used in formulation.	Complied
11.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Record of Digital data logger for temperature and humidity monitoring is provided	

Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deferred cases:

991.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.
	Details of Drug Sale License of importer	DSL No.: 1245 Address: M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.. Godown: Plot No. 10 Sector 25, K I A Karachi HT-8, Landhi Industrial Area, Karachi. Validity: 18/05/2022 Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name, address of manufacturer(s)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Original legalized CoPP (certificate No. CoPP/CERT/KD/83894/2019/11/27844/143353) valid till 03-04-2022 issued by Food and Drug Administration Mahrashtra Estate Mumbai for Methotrexate Tablets 2.5mg . The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. GMP: Firm has submitted GMP certificate No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 issued by Food and Drug Administration Mahrashtra Estate Mumbai. Valid till 03.04.2022
	Details of letter of authorization / sole agency agreement	Firm has submitted Original Authorization letter from Naprod Life Sciences Pvt. Ltd. The letter species that the manufacturer appoints M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi as a sole agent and distributor to register their products in Pakistan .
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5224: 24-02-2022
	Details of fee submitted	PKR 150,000/-: 26-01-2022
	The proposed proprietary name / brand name	ALLTREX (Methotrexate) 2.5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Methotrexate ……. 2.5 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Metabolite (L04AX03)
	Reference to Finished product specifications	BP
	Proposed Pack size	As per Policy
	Proposed unit price	As per Policy
	The status in reference regulatory authorities	Methotrexate Orion 2.5 mg tablets by Orion Pharma UK MHRA approved
	For generic drugs (me-too status)	Methotrexate Tablet 2.5mg by Werrick Pharmaceuticals (025084)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Mac Chem Products (India) Pvt. Ltd. N-211/2/10. MIDC, Boisar Thane 401506 MAHARASHTRA state India. GMP: Firm has submitted GMP certificate No. NEW-WHO-GMP/CERT/KD/74238/2018/11/24897 by Food and Drug Administration Mahrashtra Estate Mumbai. Valid till 10.09.2021
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: MTX0213042, MTX0213043, MTX0213044,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product (Methotrexate Tabs 2.5mg Mfg. By Orion Pharma, UK). Quality parameters such as Disintegration time, hardness, dissolution, average weight, thickness etc were compared. Firm has submitted Comparative Dissolution Profile for the applied product as follows Test Product Naprod Methotrexate tablet 2.5mg Reference product Orion methotrexate tablet 2.5mg Medium Water,Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). On the basis of similarity factor (f2) result i.e NLT 50 of dissolution profile of API in test product and reference product, both products are similar.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu-Alu Blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 24 months real time stability data at 30°C ± 2°C / 75% ± 5%RH of 03 batches 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches

		NT8132. NT8133, NT8134

Remarks of AD (PECXX):

USFDA approved Box warning for methotrexate tablet is as follows:

METHOTREXATE tablets, for oral use
Initial U.S. Approval: 1953

WARNING: EMBRYO-FETAL TOXICITY, HYPERSENSITIVITY REACTIONS, and SEVERE ADVERSE REACTIONS

See full prescribing information for complete boxed warning.

- **Methotrexate Tablets can cause embryo-fetal toxicity, including fetal death. For non-neoplastic diseases, Methotrexate Tablets are contraindicated in pregnancy. For neoplastic diseases, advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception. (4, 5.1, 8.1, 8.3)**
- **Methotrexate Tablets are contraindicated in patients with a history of severe hypersensitivity reactions to methotrexate, including anaphylaxis. (4, 5.2)**
- **Serious adverse reactions, including death, have been reported with methotrexate. Closely monitor for adverse reactions of the bone marrow, gastrointestinal tract, liver, lungs, skin, and kidneys. Withhold or discontinue Methotrexate Tablets as appropriate. (5.3, 5.4, 5.5, 5.6, 5.7, 5.8)**

Sr.#	Observation	Reply	Remarks
1.	RRA approved formulations are Methotrexate sodium/disodium (eq to Methotrexate) while applied product is in base form. Clarify it or provide reference regarding applied formulation (base form) in any reference country.	Relevant reference is provided by the firm as follows: MHRA approved product Methotrexate tablet 2.5mg by Sandoz Ltd	Verified MHRA approved product Methotrexate tablet 2.5mg by Sandoz Ltd is also approved in base form. Each tablet contains methotrexate 2.5 mg
2.	Compatibility of the Drug Substance(s) with excipients (Sodium Lauryl Sulphate, sodium starch glycolate, colloidal silicon dioxide) is not provided	Excipients used in formulation do not influence physicochemical property of Drug product and are routinely used in pharmaceutical industry	Sodium starch glycolate is found in RRA (MHRA) approved formulation By Cipla (EU) Limited However Compatibility of the Drug Substance(s) with Sodium Lauryl Sulphate and colloidal silicon dioxide is required.
	Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.		

Decision 324th meeting: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Updated status:
Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023 wherein it has been mentioned that:
"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.
Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs."

S.No	Generics	Brand Name
	Capecitabine 500mg TAB	NAPROCAP -500
	Methotrexate 2.5mg TAB	ALLTREX
	Doxorubicin HCl for inj 50mg	NAPRODOX 50
	Leucovorin Calcium inj. 300mg	CAFONATE
	Fluorouracil inj. 500mg	FLUONCO
	Bicalutamide 50mg TAB	MACABI
	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Decision: Deferred for following requirements:

- **Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through e-mail.**
- **Compatibility of the Drug Substance(s) with excipients such as Sodium Lauryl Sulphate and colloidal silicon dioxide .**

992.	Name, address of Applicant / Marketing Authorization Holder	ATCO Laboratories Limited Address: B-18,S.I.T.E., Karachi - 75700,Karachi.Sindh
	Name, address of Manufacturing site.	ATCO Laboratories Limited Address: B-18,S.I.T.E., Karachi - 75700,Karachi.Sindh
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/12/2020 based on inspection conducted on 06/11/2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 18/03/2021 specifying lotion (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11039 dated 06/05/2022
	Details of fee submitted	PKR 30,000/- dated 11/03/2022
	The proposed proprietary name / brand name	Betaderm-N Lotion

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains Betamethasone……1mg (0.1% w/v) (as Betamethasone valerate) Neomycin sulphate……..5mg (0.5% w/v)
	Pharmacotherapeutic Group of (API)	Betamethasone (D07XC01) Corticosteroids, potent, other combinations Neomycin (D06AX04) Other antibiotics for topical use
	Pharmaceutical form of applied drug	Topical Lotion
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	10mL, 20mL, 30mL, 60mL & 120mL.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	Not found Internationally same formulation is available (UK) in cream form.
	For generic drugs (me-too status)	Betnovate-N Lotion GlaxoSmithKline (GSK)
	Name and address of API manufacturer.	BETAMETHASONE VALERATE Symbiotica Speciality Ingredients Sdn. Bhd. Kedah Malaysia. NEOMYCIN SULPHATE Yichang Sanxia Pharmaceuticals Co., Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: BETAMETHASONE VALERATE Accelerated:40°C±2°C/75%±5%RH for 6 months (BV008/0101, BV009/0101, BV010/0101) Real time:30°C±2°C/65% ± 5%RH for 60 months (BV008/0201, BV009/0201, BV010/0201) NEOMYCIN SULPHATE Real time:30°C±2°C/75% ± 5%RH for 60 months

		(201409017, 201409021, 201409023) Accelerated:40°C±2°C/75%±5%RH for 6 months (201005033, 201005034, 201005036)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Betnovate-N Lotion by GSK (Batch No NW5X) against Test product (Batch No FE075C) parameters such as identification, and Assay were compared.
	Analytical method validation of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	BETAMETHASONE VALERATE Symbiotica Speciality Ingredients Sdn. Bhd. Kedah Malaysia. NEOMYCIN SULPHATE Yichang Sanxia Pharmaceuticals Co., Ltd.		
API Lot No.	BV-BLT263/0120 (Betamethasone Valerate) 202004009 (Neomycin Sulphate)		
Description of Pack (Container closure system)	60ml in Plastic bottle packed in Printed Carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	FE075C	FE079C	FE080C
Batch Size	2000 ml	2000 ml	2000 ml
Manufacturing Date	03/2021	03/2021	03/2021
Date of Initiation	15/03/2021	15/03/2021	15/03/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
	Reference of previous approval of applications with stability study data of the firm (if any)	Rofl 500mg tablet Approved in DRB 277 held on 27-29 December 2017.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	BETAMETHASONE VALERATE National Pharmaceutical Agency Ministry of Health Malaysia GMP certificate No 1279/19 dated 11.07.2019 valid till 3years. Validity: 28/06/2022 till 27/07/2025 NEOMYCIN SULPHATE

		Department of Agriculture and Rural Affairs of Hubei Province issue date 5th November 2020. GMP certificate No: 2020 Animal Drugs GMP, No 17008 Validity: 20/11/2020 till 04/11/2025
	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
1.	Since applied formulation is not approved by any Reference Regulatory Authority hence provide safety and efficacy data regarding applied formulation in the light of decision of 128th meeting of Authority.	Mentioned below	
2.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided	Complied
3.	Provide reference wherein formulation/ingredients of Betnovate-N Lotion by GSK has been mentioned against which applied formulation has been developed.	Formulation/ingredients related data of Betnovate-N lotion by GSK is not available.	
4.	Analytical method validation studies of Drug Substance to be provided from Finished Product Manufacturer.	Analytical method validation studies of both Drug Substances have been provided including parameters such as accuracy, precision (repeatability) specificity and Range.	Complied
5.	Provide image/snapshot/picture of comparator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Image/snapshot/picture of Innovator pack is provided:	Complied

	Neither Drug substance manufacturer nor Drug product manufacturer had performed it.	Betnovate-N Lotion by GSK (Batch No NW5X) Exp date: 04/2023	
6.	Documents for the procurement of API wherein Lot No/Batch No was mentioned.	Documents for the procurement of API yet to be provided wherein Lot No/Batch No clearly mentioned	Not complied

Response to query No. 1 :

In respect of "evidence of approval status in RRA" we would like to explain you that this product is marketed by a well reputed multinational company in Pakistan namely M/s. Glaxosmith Kline under the brand name Betnovate-N Lotion [Betamethasone 0.1% w/v (as Betamethasone valerate BP) + Neomycin sulphate 0.5% w/v]. This product is not marketed in SRA countries due to the fact that the condition for use is not very much common/pandemic in reference countries that's why the multinational manufacturer, M/s. Glaxosmith Kline is marketing this product in Pakistan rather in reference countries due to public interest.

Moreover, internationally the same strength in "Cream" dosage form is marketed in UK by Chemidex Pharma Limited, Trading as Essential Generics, Chemidex House, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, United Kingdom therefore, it is confirmed that both ingredients in their respective strengths are safe irrespective of the dosage form and not withdrawn from market due to safety, efficacy and quality reasons.

Decision 331st meeting: Registration Board deferred the application for further deliberations regarding the confirmation of reply submitted by the applicant".

Reply:

Betnovate-N Lotion [Betamethasone 0.1% w/v (as Betamethasone valerate BP) + Neomycin sulphate 0.5% w/v] is marketed by a well reputed multinational company in Pakistan namely M/s. Glaxosmith Kline-GSK but not in SRA countries due to the fact that this product is indicated in certain skin conditions that is highly prevalent in Pakistan as compare to other countries, because of the hot and humid climate favoring bacterial growth, overcrowding and poor hygiene in some areas. There is a dire need of this formulation in lotion dosage form in our country. It is essential to market the said product in lotion form, in Pakistan due to the fact that this product is needed by patients suffering from inflammatory and pruritic manifestations of steroid responsive dermatoses where secondary bacterial infection is present, suspected, or likely to occur that affects larger body areas. The dosage form of lotion is of immense importance due to its attribute of greater spreadability and absorption thus, it provides faster relief of symptoms. Currently, the formulation is marketed in cream dosage form which is insufficient to be applied on largely affected areas of the body.

Moreover, the prescriber has only one choice to prescribe for the said skin condition i.e. Betnovate-N Lotion, and thus did not get chance to switch over the product by prescribing other brands as the formulation is only available in cream dosage form.

Following key points have been highlighted below for concise comparison between both dosage forms:

S.no.	Lotion	Cream
	Greater spreadability, suitable for the application on large affected areas	Difficult to spread, not suitable for the a large affected areas
	Faster absorption	Slower absorption
	Fast symptom relief	Delayed relief
	More permeable	Less permeable

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

i. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
ii. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
iii. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
iv. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

993.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4786 dated 21/02/2022
	Details of fee submitted	PKR 30,000/-: dated 07/2/2022
	The proposed proprietary name / brand name	Lura Tablet 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Lurasidone HCl……....80mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	To treat Schizophrenia and Bipolar disorder
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	10’s, 30’s
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	USFDA approved Latuda tablet
	For generic drugs (me-too status)	Lurisa 80mg tablet M/s Helix Pharma Reg No 089359
	GMP status of the Finished product manufacturer	GMP certificate dated 07.10.2021 based on inspection dated 15.06.2021 valid for two years.

		Tablet General section has been approved by CLB in 282nd meeting and letter issued dated 30.09.2021.
	Name and address of API manufacturer.	Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B# 101101, B#101201, B# 101202
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Lurisa 80mg Tablet Batch No Q003 by M/s Helix Pharma (Pvt) Ltd, by performing quality tests (Appearance, identification Assay, Dissolution, DT and average weight) against Test product Lura Tablet 80mg. Batch No21SB(A)173-01 CDP has been performed against the same brand that is Lurisa 80mg Tablet Batch No Q003 in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8) against Test product Lura Tablet 80mg. Batch No21SB(A)173-01 The values for f1 and f2 are in the acceptable range.
	Analytical method validation studies of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu.	
API Lot No.	0200-202104001	

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	21SB(A)-173-01	21SB(A)-174-02	21SB(A)-175-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Not Provided
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No JS2020921 in the name of Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu valid till 20.09.2025
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided
Remarks of Assessor (DD PEC XX): Box warning by USFDA for approved product as follows:		

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LATUDA is not approved for the treatment of patients with dementia-related psychosis *[see Warnings and Precautions (5.1)]*.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adults in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions (5.2)]*.

CLOSE

Sr.#	Observation	Reply	Remarks
1.	The finished product specification and stability testing includes quality parameter of microbiological testing and water content as per public assessment report of innovator product while same has not been performed by the applicant. (microbial test performed at initial time point only) https://www.ema.europa.eu/en/documents/assessment-report/latuda-epar-public-assessment-report_en.pdf	water content test was performed during development studies but not incorporated in specification. Now the firm has provided revised specification including water content test and microbiological testing along with performance reports.	Complied Fee of Rs 7500/- to be submitted on account of pre-registration variation
2.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) to be provided.	Provided	Complied
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	Not complied

Decision 329th meeting: Deferred for following submissions:
Submission of documents for the procurement of API with approval from DRAP
Submission of fee for pre-approval variation in finished product specification as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply:
Firm has provided fee of Rs 7500/- dated 24.08.2023 on account of pre-registration variation.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

994.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot No 69/2, Phase –II , Industrial area Hattar
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69/1, Block B, Phase-I&II, Industrial Estate Hattar.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 03.06.2019 based on inspection dated 20-05-2019
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24967 dated 02/09/2022
	Details of fee submitted	PKR 75,000/- dated 07/04/2022
	The proposed proprietary name / brand name	Nefcon 1mg/ml eye drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Nepafenac ……1mg (0.1%)
	Pharmacotherapeutic Group of (API)	NSAID, Ant inflammatory
	Pharmaceutical form of applied drug	Eye drops
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nevanac eye drops MHRA approved
	For generic drugs (me-too status)	Neplo ophthalmic solution Alza Pharmaceutical 081620
	Name and address of API manufacturer.	M/s Flax Laboratories, Plot No B-29/I, MIDC Mahad. Village Birwadi, Mahad, District Raigad India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No: NEP/MS/18/001, NEP/MS/18/002, NEP/MS/18/003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against reference product i.e Nevanac 0.1% Eye drops (Batch No 12) by Novartis Pharmaceuticals against Test product PD 01 Quality parameters compared were description, volume, identification and assay
	Analytical method validation of product	Not provided

STABILITY STUDY DATA			
Manufacturer of API	M/s Flax Laboratories, Plot No B-29/I, MIDC Mahad. Village Birwadi, Mahad, District Raigad India		
API Lot No.	NEP/MS/21/003		
Description of Pack (Container closure system)	LDPE bottle with polystyrene cap		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-15	T-16	T-17
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	July 2021	July 2021	July 2021

Date of Initiation	12.07.2021	12.07.2021	12.07.2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 6097475 issued by Food and Drug Administration Maharashtra state valid till 12.01.2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 wherein 60 g Nepafenac (Batch No NEP/MS/21/003) was mentioned (Lic No 00649/2021-DRAP CRS/2291 dated 23-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor:

S.No	Observations	Reply	Remarks
1	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Not provided	Not complied
2	Provide Elucidation of structure and other characteristics (NMR, MS, IR spectrum)	Provided	Complied
4.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Provided	Complied
5.	Provide certificate of analysis of relevant batch (NEP/MS/21/003) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	Provided	Complied
6.	3.2.P.2 Suitability /Quality testing of the container closure system used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP) to be provided	Provided	Complied
7.	3.2.P.2.2.1 Provide Pharmaceutical Equivalence against reference/comparator product wherein	Nevanac 0.1% Eye drops (Batch No 25463) by Novartis	Image/snapshot/picture

	all quality parameters (as per Innovator) should be compared. Also provide image/snapshot/picture of comparator product Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date		of innovator product yet to be provided
8.	Quality test such as osmolality /osmolarity, viscosity and sterility test have not been included under finished product specification	osmolality /osmolarity and sterility test have been mentioned mentioned under finished product specification	Viscosity test and performance report of sterility test is still required.
9.	3.2.P.5 Analytical Method Validation studies of Drug Product by the Drug Product manufacturer to be provided	Provided	Specificity parameter has not been studied.
10.	3.2.P.8 Sterility test, viscosity and osmolality /osmolarity have not been performed during stability studies.	Osmolality /osmolarity and sterility test have been provided under stability studies	Viscosity test and performance report of sterility test is still required.
11.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is Provided	

Decision 331st meeting:
Decision: Deferred for following:
a) Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer
b) Provide details of reference against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date
c) Viscosity test and performance report of sterility test to be provided
d) Results of specificity parameter under Analytical Method Validation studies of Drug Product to be provided.

Reply:
Firm has provided copy of GMP certificate No 6111950 issued by Food and Drug Administration Maharashtra state valid till 13.03.2024.
Details of reference against which pharmaceutical equivalence study was performed is provided as follows:
Nevanac 0.1% Eye drops (Batch No 25463) by Novartis
Exp date 05-2023
Result of viscosity test and performance report of microbial test has been provided.
Result of specificity parameter under Analytical Method Validation studies of Drug Product is provided.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

995.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot No 69/2, Phase –II , Industrial area Hattar

	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69/1, Block B, Phase-I&II, Industrial Estate Hattar.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 03.06.2019 based on inspection dated 20-05-2019
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24966 dated 02/09/2022
	Details of fee submitted	PKR 75,000/- dated 07/04/2022
	The proposed proprietary name / brand name	Oflexx 0.3% eye drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ofloxacin …….3mg (0.3%)
	Pharmacotherapeutic Group of (API)	Fluoroquinolone
	Pharmaceutical form of applied drug	Eye drops
	Reference to Finished product specifications	USP specification
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exocin Eye drops solution MHRA approved
	For generic drugs (me-too status)	Polycin ophthalmic solution Polyfine Chempharma 081740
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co Ltd Coastal Industrial city, Pubagang town Sanmen Country China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No: 0603038, 0603039, 0603037
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against comparator product i.e Oflocin 0.3% Eye drops (Batch No 423) by Helix pharma against Test product PD-01 Quality parameters compared were description, volume, identification and assay
	Analytical method verification of product	Not provided

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co Ltd Coastal Industrial city, Pubagang town Sanmen Country China		
API Lot No.	DC-002-2012001		
Description of Pack (Container closure system)	LDPE bottle with polystyrene cap		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-12	T-13	T-14
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	17.05.2021	17.05.2021	17.05.2021

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate (No ZJ20160079) dated 12/12/2016 Validity 15.08.2021 issued by China Food and Drug administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. of 210417-L dated 17/04/2021 wherein 0.5Kg Ofloxacin (Batch No DC-002-2012001) was mentioned. Approved by (I&E) DRAP, Peshawar dated 06.05.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided .
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided .

Remarks of Assessor:

S.No	Observations	Reply	Remarks
1	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	DML of API Manufacturer (No Zhe 20000312) issued by Zhejiang Medical Product Administration valid till 07.10.2024 is provided	Complied
2	3.2.S.1 Provide Elucidation of structure and other characteristics (IR spectrum)	Not provided	Not complied
3	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided	Not provided	Not complied
4.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Not provided	Not complied
5.	3.2.S.4 Provide certificate of analysis of relevant batch (DC-002-2012001) of Drug Substance(s) used in product development by Drug Substance manufacturer.	Provided	Complied
6.	3.2.P.2 Suitability /Quality testing of the container closure system used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and	Provided	Complied

	light, compatibility of the materials with the FPP) to be provided		
7.	3.2.P.2.2.1 Provide Pharmaceutical Equivalence against reference/comparator product wherein all quality parameters (as per USP) should be compared. Also provide image/snapshot/picture of comparator product Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Oflocin 0.3% Eye drops (Batch No 423) by Helix pharma Exp date 10/2023	Complied
8.	3.2.P.5: Quality test such as sterility test has not been included under finished product specification (as Mentioned in USP)	Sterility test has been included in finished product specification	Performance report of sterility test is still required.
9.	3.2.P.5 Analytical Method Verification studies of Drug Product by the Drug Product manufacturer to be provided	Not provided	Not complied
10.	3.2.P.8 Sterility test has not been performed during stability studies.	Sterility test is found mentioned in stability data	Performance report of sterility test is still required.
11.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is Provided	

Decision 331st meeting: Deferred for following:
Elucidation of structure and other characteristics (IR spectrum) to be provided
Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided.
Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies to be provided.
Performance report of sterility test to be provided
Analytical Method Verification studies of Drug Product by the Drug Product manufacturer to be provided

Reply:
Elucidation of structure and other characteristics (IR spectrum) are provided
Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer yet to be provided.
Method used for analysis of API from Finished Product Manufacturer has been provided
Performance report of sterility has been provided
Analytical Method Verification studies of Drug Product yet to be provided

Decision: Approved.

- **Before issuance of registration letter firm will submit Analytical verification report of both Drug substance as well as Drug Product performed by Drug Product manufacturer.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

996.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 612 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 30.11.2022
	The proposed proprietary name / brand name	LEVOTEL 250mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin as hemihydrate.....250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 250mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 250mg (Reg. No.: 026164) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tavanic 250 mg tablet by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, disintegration time). CDP has been performed against the same brand that is Tavanic 250 Tablet by sanofi aventis (Batch no. B0029) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8) against test product (Batch no. T001). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
API Lot No.	Not provided
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	5-2022	5-2022	5-2022
Date of Initiation	23-05-2022	23-05-2022	23-05-2022
No. of Batches	03		
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided	
Remarks of Assessor (DD PECXX): 1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin 3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture. 3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided 3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer. 3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards. 3.P.2.1.1Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product. 3.2.P.8 Documents for the procurement of API to be submitted. 3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.			
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.			

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	Not complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product	Not provided	Not complied Later on firm provided reference of USFDA approved formulation i.e Levaquin wherein said ingredients have been used in formulation.
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No 156322) dated 22.04.2022 batch No DC-004-200312 2.5KG API was imported.	Approval from DRAP to be provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of	Provided	Complied

	Analysis (COA) of the same batch from Drug Substance / API manufacture.		
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. Moreover, Results of specificity parameter has not been provided
Remarks:	The reply submitted against above mentioned shortcoming was found unsatisfactory.		

Decision 329th meeting: Deferred for following:
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
Submission of approval from DRAP for procurement of API.
Results of specificity parameter under Analytical Method Verification studies of Drug substance

Reply:
Firm has provided copy of DML No (Zhe 200003122) dated 10.06.2021 issued by Zhejiang Medical Product Administration, expiry date 07.10.2024
Procurement document of API, cleared by (I&E) DRAP still required.
Analytical Method Verification studies of Drug substance is provided including results of specificity parameter.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

997.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 613 dated 06.01.2023
	Details of fee submitted	PKR 30,000/-: dated 01.12.2022
	The proposed proprietary name / brand name	LEVOTEL 500mg Tablets

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Levofloxacin as hemihydrate.....500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 500mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 500mg (Reg. No.: 026163) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tavanic 500 mg tablet by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, Disintegration time). CDP has been performed against the same brand that is Tavanic 500 Tablet by sanofi Aventis (Batch No CRD0020) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8) against Test product (Batch No T001). The values for f1 and f2 are in the acceptable range. CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.		
API Lot No.		Not provided		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		5-2022	5-2022	5-2022
Date of Initiation		24-05-2022	24-05-2022	24-05-2022
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided		

	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PECXX):
1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.
3.P.2.1.1Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product.
3.2.P.2 Submit revised CDP report for Levotel tablet 500mg since CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	Not complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	Submit revised CDP report for Levotel tablet 500mg	Not provided	Not complied

	since CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)		
4.	Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product	Not provided	Not complied Later on firm provided reference of USFDA approved formulation i.e Levaquin wherein said ingredients have been used in formulation.
5.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No 156322) dated 22.04.2022 batch No DC-004-200312 2.5KG API was imported.	Approval from DRAP to be provided
6.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
7.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
8.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
9.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. Moreover Results of specificity parameter has not been provided
Remarks:	The reply submitted against above mentioned shortcoming was found unsatisfactory.		

Decision 329th meeting: Deferred for following:

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Submission of approval from DRAP for procurement of API. Results of specificity parameter under Analytical Method Verification studies of Drug substance		
Reply: Firm has provided copy of DML No (Zhe 200003122) dated 10.06.2021 issued by Zhejiang Medical Product Administration, expiry date 07.10.2024 Procurement document of API, cleared by (I&E) DRAP still required. Analytical Method Verification studies of Drug substance is provided including results of specificity parameter.		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
998.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 610 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	Sulvipride 25 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride.....25 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 25 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 25mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041008
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021

		Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:LSP0010415,LSP0020515,DC-LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Levopraid 25 mg tablet (Batch No AQ1801R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 25mg Tablet (Batch No T001) CDP has been performed against the same brand that is Levopraid 25mg Tablet by Pacific pharmaceuticals in Acid media (pH 1.0-1.2), Acetate medium (Ph 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.	

API Lot No.	LSP0260120		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	6-2022	6-2022	6-2022
Date of Initiation	4-6-2022	4-6-2022	4-6-2022
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India valid till 10.02.2022
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks Assessor (DD PECXX):
1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablets or Sulvipride 50 mg Tablet.
3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards

3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided valid GMP (No S-GMP &GLP/22023124 valid till 10.02.2024 Issued by Food and Drug control administration Gujrat	Complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.	Not provided	Not complied Later on firm has provided CDP of Sulvipride 25 mg Tablet
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No AT-018/2021-22) dated 02.05.2022 batch No LSP-0260120 0.3KG API was imported.	Approval from DRAP is required
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with	Provided	Complied

	Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.		
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. Moreover results of specificity parameter has not been provided.
Remarks	Reply submitted against above mentioned shortcomings found unsatisfactory		

Decision 329th meeting: Deferred for following:
Submission of approval from DRAP for procurement of API.
Results of specificity parameter under Analytical Method Verification studies of Drug substance

Reply:
Procurement document of API, cleared by (I&E) DRAP still required.
Firm has provided Analytical Method Verification studies of Drug substance including result of specificity parameter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

999.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 611 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	Sulvipride 50 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride.....50mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotic

	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 50mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041012
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:LSP0010415,LSP0020515,DC-LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Levopraid 50 mg tablet (Batch No AP0405R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 50mg Tablet (Batch No T001)

		CDP has been performed against the same brand that is Levopraid 50mg Tablet by Pacific pharmaceuticals in Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.		
API Lot No.	LSP0260120		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	6-2022	6-2022	6-2022
Date of Initiation	13-6-2022	13-6-2022	13-6-2022
No. of Batches	03		
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India valid till 10.02.2022	
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided	
Remarks Assessor (DD PECXX): 1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin			

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.
3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Observation	Reply	Remarks
1.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided valid GMP (No S-GMP &GLP/22023124 valid till 10.02.2024 Issued by Food and Drug control administration Gujrat	Complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.	Provided	complied
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No AT-018/2021-22) dated 02.05.2022 batch No LSP-0260120 0.3KG API was imported.	Approval from DRAP is required
5.	Compliance Record of HPLC software 21CFR & audit trail	provided	Compliance Record of HPLC software 21CFR

	reports and record of Digital data logger for temperature and humidity monitoring is not submitted.		& audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. Moreover results of specificity parameter has not been provided.
Remarks	Reply submitted against above mentioned shortcomings found unsatisfactory		
Decision 329th meeting: Deferred for following: Submission of approval from DRAP for procurement of API. Results of specificity parameter under Analytical Method Verification studies of Drug substance			
Reply: Procurement document of API, cleared by (I&E) DRAP still required. Firm has provided Analytical Method Verification studies of Drug substance including result of specificity parameter			
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			

1000.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 36729 dated 16.12.2022
	Details of fee submitted	PKR 30,000/- dated 26.10.2022
	The proposed proprietary name / brand name	CIPROTEL 250mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq.to Ciprofloxacin.....250 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO® (ciprofloxacin hydrochloride) tablet, 250 mg USFDA Approved .
	For generic drugs (me-too status)	Ciplet 250mg Tablets By M/s Indus Pharma Karachi.
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility , physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A, B,C,D & E, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 500 mg tablet (Batch No C122) by Bayer Pharma by performing quality tests (Identification, Assay, Dissolution, Average weight) against Test product (Batch No C-T001) CDP has been performed against the same brand that is Ciproxin 500 Tablet by Bayer Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	00510011/178/2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	20-10-2021	20-10-2020	20-10-2021
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.

	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PECXX):
1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.S.4 In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.
3.2.P.2: Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg tablet.
3.P.2.1.1Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are not found in innovator/reference product.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision 326th meeting : Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

S.No	Observations	Reply	Remarks
1	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Not provided	Valid GMP certificate of M/s Pharmagen is still required
2	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Complied
3	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Analytical procedures for the testing of drug substance is provided (as per USP)
4	In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.	Firm has provided result of Residue on Ignition" test performed as per USP.	Complied
5	Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance	Firm has justified quantity of API mentioned in batch	Justified

	mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg tablet	formula w,.r.t to potency adjustment (salt factor and water content)	
6	Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are not found in innovator/reference product.	Not provided	Not complied
7	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Not provided	

Decision: Approved.

- **Before issuance of registration letter firm will submit:**

a) **Valid GMP certificate of API manufacturer issued by DRAP**

b) **Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate)**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application..**

1001.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 36728 dated 16.12.2022
	Details of fee submitted	PKR 30,000/- dated 26.10.2022
	The proposed proprietary name / brand name	CIPROTEL 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq.to Ciprofloxacin.....500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones

	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO® (ciprofloxacin hydrochloride) tablet, 500 mg USFDA Approved .
	For generic drugs (me-too status)	Ciplet 500mg Tablets By M/s Indus Pharma Karachi.(Reg.# 044462)
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility , physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A, B,C,D & E, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 500 mg tablet (Batch No C122) by Bayer Pharma by performing quality tests (Identification, Assay, Dissolution, Average weight) against Test product (Batch No C-T001) CDP has been performed against the same brand that is Ciproxin 500 Tablet by Bayer Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.		00510011/178/2021		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		10-2021	10-2021	10-2021
Date of Initiation		20-10-2021	20-10-2020	20-10-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided		

	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PECXX):
1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.S.4 In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.
3.2.P.2: Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg tablet.
3.P.2.1.1Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are not found in innovator/reference product.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision 326th meeting : Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

S.No	Observations	Reply	Remarks
1	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Not provided	Valid GMP certificate of M/s Pharmagen is still required
2	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Complied
3	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Analytical procedures for the testing of drug substance is provided (as per USP)
4	In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.	Firm has provided result of Residue on Ignition" test performed as per USP.	Complied
5	Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg tablet	Firm has justified quantity of API mentioned in batch formula w,r.t to potency adjustment (salt factor and water content)	Justified
6	Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are	Not provided	Not complied

	not found in innovator/reference product.		
7	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Not provided	

Decision: Approved.

- **Before issuance of registration letter firm will submit:**

a) **Valid GMP certificate of API manufacturer issued by DRAP**

b) **Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate)**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1002.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26328 dated 19-09-2022
	Details of fee submitted	Rs.75,000/- dated 19-09-2022
	The proposed proprietary name / brand name	Pytol – C Tablets 120mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet contains: Paracetamol 120mg
	Pharmaceutical form of applied drug	Chewable tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti-pyretic drug
	Reference to Finished product specifications	USP
	Proposed Pack size	2x12's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Panadol Chewable Tablets 120mg approved by TGA (Australia)
	For generic drugs (me-too status)	N/A

<table>
<tr><td></td><td>GMP status of the Finished product manufacturer</td><td>Last inspection report dated 14.10.2021 concluded good level of cGMP compliance.</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Citi Pharma Limited 3km, Head Balloki Road, Bhai Pheru, Distt Kasur - Pakistan</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Stability studies</td><td>Stability study conditions:
Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months
Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
<table>
<tr><td>Batch No</td><td>Accelerated</td><td>Long Term</td></tr>
<tr><td>PGP-14-37</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>PGP-14-38</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>PGP-14-36</td><td>6 Months</td><td>60 Months</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Container closure and stabilities studies.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence have been established against the brand leader that is Panadol Chewable 120mg tablet by GSK (Batch No 821121) by performing quality tests (Identification, Assay, disintegration, hardness, content uniformity and Dissolution.

CDP has been performed against the same brand that is Panadol Chewable 120mg tablets (Batch No 821121) by GSK in Acid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Method verification studies have submitted including Introduction, Verification of assay method,</td></tr>
</table>

		Specificity, Accuracy, Precision, Linearity concentration and range.	
STABILITY STUDY DATA			
Manufacturer of API		Citi Pharma Limited 3.5km, Head Balloki Road, Bhai Pheru, Distt Kasur - Pakistan	
API Lot No.		PGP21-549	
Description of Pack (Container closure system)		Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24(Months)	
Batch No.		ACW-001	ACW-002
Batch Size		5000 Tab	5000 Tab
Manufacturing Date		02-2022	02-2022
Date of Initiation		19-02-2022	19-02-2022
No. of Batches		02	
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021. Registration Board decided to approve registration of EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: The HPLC software is 21 CFR compliant. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. Adequate monitoring and control are available for stability chamber. Chamber are controlled and	

		monitored through software having alarm system for alerts as well. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg. Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm had provided copy of GMP Certificate of Citi Pharma Limited 3.5km, Head Balloki Road, Bhai Pheru, Distt Kasur Pakistan (Dated 17.12.2022) GMP Valid upto: Two years
	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of EvaluatorXX: Firm has submitted specification of hardness as follows: Hardness NLT 4Kp Upper limit to be defined as USFDA recommends that hardness for chewable tablets be kept low (<12 kp). A higher hardness value (>12 kp) may be considered if justified.		
Decision 323rd meeting: Deferred for comparison of instant formulation against the innovator product for qualitative composition and manufacturing method applied by firm for masking the bitter effect of drug substance		

Reply:
Firm has provided manufacturing process flow diagram and comparison of instant formulation against the innovator product as follows:

Pytol-C ChewableTablet	Panadol Chewable Tablet (TGA approved)
Mannitol	Mannitol
Ethyl cellulose	Ethyl cellulose
Maize starch	Maize starch
Saccharin sodium	Saccharin sodium
Cherry Flavor	Cherry Flavor
Stearic acid	Stearic acid

Also provided organoleptic study which shows Pytol-C tablet is not bitter in taste.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration applications of newly granted DML or New section (Human)
New Section:
M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
CLB in its 279th meeting held on 18th February 2021, has considered and approved the grant of following additional section/facility:

Dry Powder for Injection (Cephalosporin) New.

1003.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32619 dated 14.11.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	Jaspime 1gm Injection

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine equivalent to Cefepime ……. 1000mg
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 1g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA
	For generic drugs (me-too status)	Maxum 1.0gm Injection Curexa Health Pvt LTD, a subsidiary of Highnoon Laboratories Reg. No. 090509
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin) .
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,B,C,D,E&F & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Maxum 1.0gm Injection Curexa Health Pvt LTD, Batch No 2180120 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against Jaspime injection 1.0g (Batch No KI-01)		
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China		
API Lot No.		1011AJ89DB		
Description of Pack (Container closure system)		15ml glass vial with fluorobutyl rubber stopper		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.		LH 01	LH 02	LH 03
Batch Size		100Vials	100Vials	100Vials
Manufacturing Date		11-10-2021	11-10-2021	11-10-2021
Date of Initiation		28-10-2021	28-10-2021	28-10-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB.		
	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted		

	Raw data sheets, COA, summary data sheets etc.	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (AD-PECXX):

Sr.#	Observations	Reply	Remarks
	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by China Food and Drug Administration (No SD20180660) valid till 08.02.2023 is provided	Complied
	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)	CoA of Drug substance as per USP is submitted from Drug product manufacturer wherein assay result is mentioned as 893 ug/mg (anhydrous basis) which falls within limit (825ug/mg to 911ug/mg) as per USP. The assay result obtained as 519ug/mg (on as is basis)	Complied
	Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.	CoA of Drug substance as per USP (both from Drug Product manufacturer and Drug Substance manufacturer) wherein crystallinity and water determination tests were mentioned	Complied
	The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added in reference product (USFDA approved) to control the pH of the	The ratio of L Arginine and cefepime activity	Complied

	constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.	has been provided as under: Sterile arginine : cefepime activity 0.707 : 1 In total quantity (cefepime HCl with L arginine) of 1.707g, quantity of L arginine used = 0.707g (i.e 707mg/g or 39.94%)	
	Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture	CoA of Drug substance provided from Drug Substance (from Drug product manufacturer) is provided with batch No of 1011A18906	CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted with WFI) for period of 24 hours (at 30°C ± 2°C / 65% ± 5%RH) is provided, for all three stability batches	Complied
	In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.	Stability study report is provided wherein pharmacopoeial quality parameters like BET, sterility test, water determination and uniformity of dosage unit, were tested	Complied
	Compliance Record of HPLC software 21CFR & audit trail reports on product	Provided	Complied
	Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.	Sterile water for injection is used for reconstitution. Details mentioned below: Aquakan 5ml Reg No:111993 by Jaskan pharmaceutical	Complied

	Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia	Tests and specifications of Type II glass vial is provided (including pharmacopoeial tests of hydrolytic resistance i.e glass surface test and glass grain tests)	Complied
	Justify selection of that particular comparator product. Moreover pharmaceutical equivalence study against Jaspime 500mg injection has not been performed (instead Jaspime 1000mg injection was used against Cefstar 500 mg Injection)	Innovator product is not available in Pakistan hence Maxum 1.0gm Injection Curexa Health Pvt LTD, Batch No 2180120 was selected for pharmaceutical equivalence study.	Justified
	Compatibility studies of drug product with diluent is not provided.	No any incompatibility is recorded with diluent.	
	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Calculation provided including assay result, LOD and Arginine content.	Calculation regarding potency adjustment (salt factor) is not provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Decision 326th meeting:
Deferred for following reasons:

- CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
- Calculation regarding potency adjustment (salt factor) is to be provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Reply:
Firm has provided CoA of relevant batch (No 1011AJ89DB) from Drug product manufacturer
Calculation regarding potency adjustment w.r.t to Arginine content and water content has been provided however salt factor yet to be calculated.

Decision: Approved.

- **Before issuance of registration letter firm will submit Batch Formula wherein potency adjustment of API w.r.t salt factor should be provided.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1004.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32618 R&1 DRAP dated 14th Nov.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	Jaspime 500mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine equivalent to Cefepime ……. 500mg
	Pharmaceutical form of applied drug	Dry powder for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 0.5g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA USFDA approved
	For generic drugs (me-too status)	Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt LTD Reg. No. 030953
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin) .
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 Dongjia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,B,C,D,E&F & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against comparator product Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt Ltd Batch No. C5824 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against Jaspime injection 1.0g (Batch No LI-01)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc

STABILITY STUDY DATA	
Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China
API Lot No.	1011AJ89DB
Description of Pack (Container closure system)	15ml glass vial with fluorobutyl rubber stopper
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,6 (Months)

		Real Time: 0, 3, 6 (Months)		
Batch No.		LI 01	LI 02	LI 03
Batch Size		100 Vials	100 Vials	100 Vials
Manufacturing Date		11-10-2021	11-10-2021	11-10-2021
Date of Initiation		28-10-2021	28-10-2021	28-10-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Assessor (AD-PECXX):

Sr.#	Observations	Reply	Remarks
	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by China Food and Drug Administration (No SD20180660) valid till 08.02.2023 is provided	Complied
	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)	CoA of Drug substance as per USP is submitted from Drug product manufacturer wherein assay	Complied

		result is mentioned as 893 ug/mg (anhydrous basis) which falls within limit (825ug/mg to 911ug/mg) as per USP. The assay result obtained as 519ug/mg (on as is basis)	
	Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.	CoA of Drug substance as per USP (both from Drug Product manufacturer and Drug Substance manufacturer) wherein crystallinity and water determination tests were mentioned	Complied
	The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added in reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.	The ratio of L Arginine and cefepime activity has been provided as under: Sterile arginine : cefepime activity 0.707 : 1 In total quantity (cefepime HCl with L arginine) of 1.707g, quantity of L arginine used = 0.707g (i.e 707mg/g or 39.94%)	Complied
	Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture	CoA of Drug substance provided from Drug Substance (from Drug product manufacturer) is provided with batch No of 1011A18906	CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted with WFI) for period of 24 hours (at 30°C ± 2°C / 65% ± 5%RH) is provided, for all three stability batches	Complied

	In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.	Stability study report is provided wherein pharmacopoeial quality parameters like BET, sterility test, water determination and uniformity of dosage unit, were tested	Complied
	Compliance Record of HPLC software 21CFR & audit trail reports on product	Provided	Complied
	Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.	Sterile water for injection is used for reconstitution. Details mentioned below: Aquakan 5ml Reg No:111993 by Jaskan pharmaceutical	Complied
	Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia	Tests and specifications of Type II glass vial is provided (including pharmacopoeial tests of hydrolytic resistance i.e glass surface test and glass grain tests)	Complied
	Justify selection of that particular comparator product. Moreover pharmaceutical equivalence study against Jaspime 500mg injection has not been performed (instead Jaspime 1000mg injection was used against Cefstar 500 mg Injection)	Innovator product is not available in Pakistan hence Cefstar 500mg Injection by Barrett Hodgson Pvt Ltd, Batch No C5824 was selected for pharmaceutical equivalence study. Moreover, revised/corrected pharmaceutical equivalence study is submitted by performing quality tests against Jaspime injection 500mg (Batch No LI-01)	Justified
	Compatibility studies of drug product with diluent is not provided.	No any incompatibility is	

		recorded with diluent.	
	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Calculation provided including assay result, LOD and Arginine content.	Calculation regarding potency adjustment (salt factor) is not provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Decision 326th meeting:
Deferred for following reasons:

- CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
- Calculation regarding potency adjustment (salt factor) is to be provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Reply:
Firm has provided CoA of relevant batch (No 1011AJ89DB) from Drug product manufacturer
Calculation regarding potency adjustment w.r.t to Arginine content and water content has been provided however salt factor yet to be calculated.

Decision: Approved.

- **Before issuance of registration letter firm will submit Batch Formula wherein potency adjustment of API w.r.t salt factor should be provided.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1005.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34288 dated 28.11.2022

	Details of fee submitted	PKR 30,000/- dated 10.11.2022
	The proposed proprietary name / brand name	Combrain 200mcg + 6mcg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Budesonide……200mcg Formoterol fumarate…..6mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	Corticosteroid and Long acting β2 adrenergic agonist.
	Reference to Finished product specifications	As per innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Symbicort turbohaler 200mcg + 6mcg inhalation powder MHRA approved
	For generic drugs (me-too status)	Venticort Rota capsule Macter International Reg. No. 081177
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for three years. New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Formoterol fumarate dihydrate The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A&F, unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance Budesonide: The firm as submitted detail of nomenclature, structure, general properties, solubility,

		physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,L,D,K & unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Formoterol fumarate dihydrate Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FF-0071013 M, FF-0010514 and FF-0010515 M) Budesonide: Real time: 30°C ± 2°C / 75% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(BDS-0071216, BDS-0010415 and BDS-0020514)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence of Eye Drop dosage form is performed. Moreover comparator product is to be clarified.
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.

STABILITY STUDY DATA			
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Not provided		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-27	T-28	T-29
Batch Size	500 Caps	500 Caps	500 Caps

Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	28-11-2021	28-11-2021	28-11-2021
No. of Batches	03		
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)	
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided	

Remarks of Assessor (DD PECXX):

Label claim of RRA approved formulation (Symbicort® Turbohaler® 200 micrograms/6 micrograms/ powder for inhalation) is as follows:

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.
Each metered dose contains: budesonide 200 micrograms/inhalation and formoterol fumarate dihydrate 6 micrograms/inhalation.
Firm has not provided information regarding delivered dose

3.2.P.2 In reference product quantity of Lactose monohydrate used is 730microgram while in applied formulation the quantity of Lactose monohydrate used was 50mg. justify it

3.2.P.2 In reference product Lactose monohydrate is the only excipient been used while firm used other excipients as well such as Talcum powder, Macragol 100, Povidone, Aerosil 200 . justify it, also provide Drug-Excepient compatibility studies of said excipients.
3.2.P.2 The container closure system of reference product, is an inspiratory flow-driven, multidose powder inhaler containing metered doses which is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.

3.2.P.5 Specification of Dug Product did not include water content test which is critical quality parameters for DPI.
3.2.P.2 Pharmaceutical equivalence study to be performed including all quality parameters, Moreover, name batch no and manufacturer of both Test product and Reference product to be provided.
3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.
3.2.P.2 Potency adjustment (salt factor) calculation was not provided for Formoterol fumarate dihydrate in Batch formula.
3.2.P.2 Detailed Analytical testing method of Drug Product to be provided.
3.2.P.2 Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device (name, model, manufacturer and shelf life) provided in pack.
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 CoA of Drug Substance Formoterol fumarate dihydrate particle size distribution test was not performed which is critical quality attribute in applied formulation i.e DPI.

Decision 326th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section

Reply:

Sr.#	Section	Observations	Reply	Remarks
1.		Label claim of RRA approved formulation (Symbicort® Turbohaler® 200 micrograms/6 micrograms/ powder for inhalation) is as follows: Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation. Each metered dose contains: budesonide 200 micrograms/inhalation and formoterol fumarate dihydrate 6 micrograms/inhalation. Firm has not provided information regarding delivered dose	Firm has provided content of active ingredients emitted from the mouthpiece of DPI as follows: Budesonide 155 micrograms/inhalation delivered Formoterol fumarate dihydrate 4.2 micrograms/inhalation delivered Firm also provided detail of sampling apparatus (for determining content of active ingredients emitted from mouth piece)	Delivered dose of both ingredients is different from RRA approved formulation.

2.	3.2.P.2	In reference product quantity of Lactose monohydrate used is 730microgram while in applied formulation the quantity of Lactose monohydrate used was 50mg. justify it	Firm has submitted revised master formulation wherein quantity of Lactose monohydrate mentioned as 20mg	In reference product quantity of Lactose monohydrate used is 730microgram quantity mentioned yet to be justified
3.	3.2.P.2	In reference product Lactose monohydrate is the only excipient been used while firm used other excipients as well such as Talcum powder, Macragol 100, Povidone, Aerosil 200 . justify it, also provide Drug-Excipient compatibility studies of said excipients	In the earlier provided formulation excipients other than lactose monohydrate have been mentioned mistakenly. Corrected formulation is provided complying with reference product	Revised formulation as per reference product has been submitted which is qualitatively similar to reference product.
4.	3.2.P.2	The container closure system of reference product, is an inspiratory flow-driven, multidose powder inhaler containing metered doses which is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.	Applied formulation is hard gelatin capsule containing powder for inhalation along with revolizer for Administration. It contains a container closure system in which capsule is placed and inhaled from mouth piece by inspiration, this is in accordance to reference product which is inspiratory flow driven.	Justification yet to be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.
5.	3.2.P.5	Specification of Dug Product did not include water content test which is critical quality parameters for DPI.	Specification of Drug product has been submitted wherein water content test is included.	Quality tests such as uniformity of delivered dose and aerodynamic assessment of fine particles have not been performed
6.	3.2.P.2	Pharmaceutical equivalence study to be performed including all quality parameters, Moreover, name batch no and manufacturer of both Test product and Reference product to be provided.	Pharmaceutical equivalence study has been performed against comparator product: Combivair 200mcg/6mcg capsule B.No: 230519 Exp date: 07/2023 Quality parameters compared included:	Quality tests such as uniformity of delivered dose, aerodynamic assessment of fine particles and microbial contamination have not been performed

			Water content, content uniformity, assay	
7.	3.2.P.2	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Provided	Complied
8.	3.2.P.2	Potency adjustment (salt factor) calculation was not provided for Formoterol fumarate dihydrate in Batch formula	Potency adjustment/salt factor calculation for Formoterol fumarate dihydrate has been provided in batch formula.	Complied
9.	3.2.P.2	Detailed Analytical testing method of Drug Product to be provided.	Not provided	Not complied
10.	3.2.P.2	Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device (name, model, manufacturer and shelf life) provided in pack.	Detail of container closure system is provided as follows: 10 rotacap /blister (aluminium foil) Inhalation device: Name: WRLflo Model: WRL-00753 Manufacturer: Winbrain Shelf life: 5 years.	
11.	3.2.P.8	Documents for the procurement of API to be submitted.	Firm has provided copy of commercial invoice dated 26.10.2021 wherein Formoterol fumarate dihydrate EP (5gm) Batch No. FF-0090821 and Budesonide EP Batch No BDS-0510921 is mentioned .Approved by DRAP (I&E) Peshawar dated 9-11-2021	Complied
12.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Record of Digital data logger for temperature and humidity monitoring is provided	
13	3.2.S.4	Detailed analytical procedures for the testing of drug	Analytical procedures for the testing of	Complied

		substance to be provided by Drug product manufacturer	Formoterol fumarate dihydrate is submitted as per BP. Analytical procedures for the testing of Budesonide is submitted as per Ph.Eur	
14	3.2.S.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Certificate of Analysis (COA) of relevant batches of both Drug Substances have been provided by Drug Substance manufacturer Formoterol fumarate dihydrate Batch No. FF-0090821 and Budesonide Batch No BDS-0510921	Certificate of Analysis (COA) of relevant batches to be provided from Drug product manufacturer as well
15	3.2.S.4	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies of Formoterol fumarate dihydrate and Budesonide has not been provided by Drug Product manufacturer	Not complied
16	3.2.S.4	CoA of Drug Substance Formoterol fumarate dihydrate particle size distribution test was not performed which is critical quality attribute in applied formulation i.e DPI.	CoA of Formoterol fumarate dihydrate is provided wherein particle size distribution test has been included.	Complied

Also provide registration status of previously registered products for "Sachet (general) section

Decision 333rd meeting: Registration Board deferred the application for following shortcomings;
Justify quantity of Lactose monohydrate i.e 20mg per unit dose (rotacap) with reference to RRA approved formulation wherein quantity of Lactose monohydrate is mentioned as 730microgram per delvered dose.
Perform quality tests such as uniformity of delivered dose and aerodynamic assessment of fine particles under finished product specification as well as pharmaceutical equivalence study.
Provide detailed Analytical testing method of Drug Product.
Provide CoA of relevant batches of both Drug Substances used in product development from Drug Product manufacturer.
Provide Analytical Method Verification studies of both drug substances by the Drug Product manufacturer.

Reply:
There was typographic mistake in mentioning quantity of Lactose monohydrate, the correct quantity is 730mcg per unit dose in line with RRA. Master formula with correct quantity is submitted.
Results of aerodynamic assessment of fine particles have been submitted along with results and performance report for aerodynamic assessment of particles and uniformity of delivered dose.
Detailed Analytical testing method of Drug Product has been provided
CoA of relevant batches of both Drug Substances Formoterol fumarate dihydrate (Batch No. FF-009082) and Budesonide (Batch No BDS-0510921) has been provided
Analytical Method Verification studies of both drug substances have been provided by Drug Product manufacturer.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1006.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16126 dated 26-06-2023
	Details of fee submitted	PKR 30,000/- Dated 07/06/2023
	The proposed proprietary name / brand name	Azdir 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin dihydrate eq to Azithromycin……..500mg
	Pharmacotherapeutic Group of (API)	Macrolide
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	6’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azithromycin 500mg tablet USFDA approved
	For generic drugs (me-too status)	Azomax 500mg tablet by M/s AGP pharma Reg No 112798

	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Azomax 500mg tablet by AGP (Batch No T8760, Exp date 12-2024). Quality parameters such as appearance, average weight, dissolution, content uniformity, Disintegration, hardness and assay against Test product. Firm has submitted CDP results of Azithromycin 250mg capsule (instead of 500mg tablet) against the Azomax 250mg capsule (Batch No T8838) in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.		
API Lot No..Batch number	AZM2208004		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TTR025	TTR026	TTR027
Batch Size	600 tab	600 tab	600 tab
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	16/12/22	16/12/22	16/12/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied

3.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	3.2.S.4 Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.	Analytical Method Verification studies of Drug substance performed by the Drug Substance manufacturer is submitted	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided
5.	3.2.S.5 COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied
6.	3.2.S.7 Provide stability data of Drug Substance (both Accelerated and Real time) of 3 batches.	Stability data of 3 batches: AZM2101001 AZM2101002 AZM2101003 As per zone IV-A conditions Real time for 9 months Accelerated for 6 months	Complied
7.	3.2.P.2.2.1 Perform CDP of applied product (azithromycin 500mg tablet). CDP results of Azithromycin 250mg capsule (Batch No T8760) have been submitted (against the Azomax 250mg capsule Batch No T8838).	CDP report against Azomax 500mg Tablet by AGP Ltd Batch No T8760, Exp date 12/2024 is provided.	Complied
8.	3.2.P.5 Assay method is not as per USP 2023 (chromatographic conditions, quantity of diluents/mobile phase etc) adopt assay as per USP 2023 and submit accordingly.	Assay method as per USP 2023 has been submitted	
9.	3.2.P.8 Provide procurement document/commercial invoice wherein quantity, batch no and date of purchase should be mentioned.	Purchase invoice No CP22-11024 dated 08 Dec 2022 is provided wherein Azithromycin Batch No AZM2208004 is mentioned	Complied
10.	3.2.P.8 Provide stability data of Drug Product (both Accelerated and Real time) for 6th month and onward all 3 batches.	Only summary data sheet is provided for 6th month data (both Accelerated and Real time)	CoA and chromatograms to be provided.

Decision 333rd meeting: Deferred the request for submission of following documents: a) Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer. b) CoA and chromatograms of stability data of all 3 batches of Drug Product (both Accelerated and Real time) for 6th month.		
Reply: Firm has provided analytical method verification studies of Drug substance performed by the Drug Product manufacturer. CoA and chromatograms of stability data of all 3 stability batches of Drug Product (both Accelerated and Real time) are submitted for 6th month time point.		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**		
1007.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☒ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16125 dated 26-06-2023
	Details of fee submitted	PKR 30,000/- Dated 07/06/2023
	The proposed proprietary name / brand name	Azdir 250mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Azithromycin dihydrate eq to Azithromycin……..250mg
	Pharmacotherapeutic Group of (API)	Macrolide
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	6's, 10's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax 250mg capsule Pfizer Limited MHRA approved
	For generic drugs (me-too status)	Azomax 250mg capsule by M/s AGP pharma Reg No 112797
	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Azomax 250mg capsule by AGP (Batch No T8838). Quality parameters such as appearance, average weight, dissolution, content uniformity, Disintegration and assay against Test product. Firm has submitted CDP results of Azithromycin 500mg tablet (instead of 250mg capsule) against the Azomax 500mg Tablet (Batch No T8760) in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5)

		& Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.		
API Lot No..Batch number	AZM2208004		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CTR025	CTR026	CTR027
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	16/12/22	16/12/22	16/12/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.	

2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied
3.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	3.2.S.4 Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.	Analytical Method Verification studies of Drug substance performed by the Drug Substance manufacturer is submitted	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided
5.	3.2.S.5 COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied
6.	3.2.S.7 Provide stability data of Drug Substance (both Accelerated and Real time) of 3 batches.	Stability data of 3 batches: AZM2101001 AZM2101002 AZM2101003 As per zone IV-A conditions Real time for 9 months Accelerated for 6 months	Complied
7.	3.2.P.2.2.1 Perform CDP of applied product (azithromycin 250mg capsule) CDP results of Azithromycin 500mg tablet have been submitted (against Azomax 500mg Tablet Batch No T8760).	CDP report against Azomax 250mg capsule by AGP Ltd Batch No T8838, Exp date 12/2024 is provided.	Complied
8.	3.2.P.5 Water content test has not been performed as per USP.	Water content test has been performed by Karl fischer method	Performance report has not been provided
9.	3.2.P.8 Provide procurement document/commercial invoice wherein quantity, batch no and date of purchase should be mentioned.	Purchase invoice No CP22-11024 dated 08 Dec 2022 is provided wherein Azithromycin Batch No AZM2208004 is mentioned	Complied
10.	3.2.P.8 Provide stability data of Drug Product (both Accelerated and Real time) for 6th month and onward all 3 batches.	Only summary data sheet is provided for 5th month data (both Accelerated and Real time)	CoA and chromatograms to be provided.

Decision 333rd meeting: Registration Board deferred the request for submission of following documents: Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer. CoA and chromatograms of stability data of of all 3 batches of Drug Product (both Accelerated and Real time) for 6th month. Performance report Water content test as per USP
Reply: Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer has been provided. CoA and chromatograms of stability data of all 3 stability batches of Drug Product (both Accelerated and Real time) are submitted for 6th month time point. Results of water content test performed by Karl Fischer method has been provided for each stability batch.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1008.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided copy of GMP certificate No F.3-20/2019-DRAP -40 dated 03.06.2019 based on inspection dated 20.05.2019 valid till 19.05.2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 24-06-2011 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28257 dated 05-10-2022
	Details of fee submitted	PKR 30,000/- Dated 23/09/2022
	The proposed proprietary name / brand name	Avtor 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Atorvastatin as Calcium Trihydrate……...20mg

	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors
	Pharmaceutical form of applied drug	film coated tablet
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Lipirex tablet 20mg M/s Highnoon Laboratories Ltd Reg No 030504
	Name and address of API manufacturer.	M/s Morepen Laboratories Ltd Malkumajra, Nalagarh Road, Distt Solan, H.P, 173 205 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(5616010201, 5616010202 and 5616010203)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against Lipirex 20mg Tablet by Highnoon Laboratories Ltd (B.No 220330) Firm has submitted CDP results against the Lipirex 20mg Tablet by Highnoon Laboratories Ltd in acidic medium (0.1 NHCl), acetate buffer (Ph 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method Validation study	Only summarized tabulated results have been provided instead of detailed Analytical method Validation study of Drug Product

STABILITY STUDY DATA			
Manufacturer of API	M/s Morepen Laboratories Ltd Malkumajra, Nalagarh Road, Distt Solan, H.P, 173 205 India		
API Lot No	ATC 7063		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-28	T-29	T-30
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02/22	02/22	02/22
Date of Initiation	16-02-2022	16-02-2022	16-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice (No M/BE/2021-2022/0058) Dated 02-01-2022 wherein Atorvastatin calcium 1Kg Batch No ATC 7063 has been mentioned. Approval from DRAP (I&E) is required
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

	Remarks of Assessor: Sr.# | Observations 1. | Provide updated GMP status of finished product manufacturer 2. | Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided 3. | 3.2.S.4 Clarify specifications of Drug Substance. Since CoA (from DS manufacturer) and analytical method of Drug Substance (by Drug Product manufacturer) were not according to USP (as claimed by DS manufacturer). Moreover submit analytical method verification studies of Drug substance accordingly. 4. | 3.2.S.4 Provide CoA of relevant batch (ATC 7063) by finished product manufacturer 5. | 3.2.P.2.2.1 Provide details of comparator product i.e Lipirex 10mg Tablet such as Exp. Date, Batch no. etc 6. | 3.2.P.5 Provide detailed analytical testing method adopted for analysis of Drug product. 7. | 3.2.P.8 Justification to be provided for selection of dissolution parameters i.e dissolution medium (0.01 M HCl), rpm (50), sampling time (30min) as mentioned under stability study 8. | 3.2.P.8 Provide documents for the procurement of API with approval from DRAP.
Decision: Deferred for submission of above mentioned shortcomings.	

1009.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided copy of GMP certificate No F.3-20/2019-DRAP -40 dated 03.06.2019 based on inspection dated 20.05.2019 valid till 19.05.2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 24-06-2011 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28382 dated 06-10-2022
	Details of fee submitted	PKR 30,000/- Dated 23/09/2022
	The proposed proprietary name / brand name	Avtor 10mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Atorvastatin as Calcium Trihydrate……...10mg
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors
	Pharmaceutical form of applied drug	film coated tablet
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Lipirex tablet 10mg M/s Highnoon Laboratories Ltd Reg No 030503
	Name and address of API manufacturer.	M/s Morepen Laboratories Ltd Malkumajra, Nalagarh Road, Distt Solan, H.P, 173 205 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(5616010201, 5616010202 and 5616010203)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against Lipirex 10mg Tablet by Highnoon Laboratories Ltd (B.No PD T-25) Firm has submitted CDP results against the Lipirex 10mg Tablet by Highnoon Laboratories Ltd in acidic medium (0.1NHCl), acetate buffer (Ph 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method Validation study	Only Summarized tabulated results have been provided instead of detailed Analytical method Validation study of Drug Product

STABILITY STUDY DATA			
Manufacturer of API	M/s Morepen Laboratories Ltd Malkumajra, Nalagarh Road, Distt Solan, H.P, 173 205 India		
API Lot No	ATC 7063		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-25	T-26	T-27
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02/22	02/22	02/22
Date of Initiation	16-02-2022	16-02-2022	16-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice (No M/BE/2021-2022/0058) Dated 02-01-2022 wherein Atorvastatin calcium 1Kg Batch No ATC 7063 has been mentioned. Approval from DRAP (I&E) is required
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided
3.	3.2.S.4 Clarify specifications of Drug Substance. Since CoA (from DS manufacturer) and analytical method of Drug Substance (by Drug Product manufacturer) were not according to USP (as claimed by DS manufacturer). Moreover submit analytical method verification studies of Drug substance accordingly.
4.	3.2.S.4 Provide CoA of relevant batch (ATC 7063) by finished product manufacturer
5.	3.2.P.2.2.1 Provide details of comparator product i.e Lipirex 10mg Tablet such as Exp. Date, Batch no. etc
6.	3.2.P.5 Provide detailed analytical testing method adopted for analysis of Drug product.
7.	3.2.P.8 Justification to be provided for selection of dissolution parameters i.e dissolution medium (0.01 M HCl), rpm (50), sampling time (30min) as mentioned under stability study
8.	3.2.P.8 Provide documents for the procurement of API with approval from DRAP.

Decision: Deferred for submission of above mentioned shortcomings.

1010.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Pvt Ltd 112/10 Quaid-e-azam Industrial Estate, Kot Lakhpat Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10 Quaid-e-azam Industrial Estate, Kot Lakhpat Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided copy of GMP certificate No 105/2020-DRAP (AD-1926898-790) dated 06-07.2020 based on inspection dated 04.03.2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of approval letter for grant of additional section dated 25.06.2019 wherein Sachet (General) section was mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29617 dated 18-10-2022
	Details of fee submitted	PKR 30,000/- Dated 26/04/2022
	The proposed proprietary name / brand name	Ostocare Sachet 2g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Strontium Ranelate ……....2g
	Pharmacotherapeutic Group of (API)	Postmenopausal Osteoporosis,
	Pharmaceutical form of applied drug	Oral Dry Powder granules
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	7 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aristo 2g sachet Aristo Pharma Germany MHRA approved
	For generic drugs (me-too status)	Osstium 2g sachet Atco Laboratories Reg No 058698
	Name and address of API manufacturer.	M/s Suntril Pharmaceuticals Pvt. Ltd Plot No 219, Phase I, HSIIDC, Alipur Barwala, Haryana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 9 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6months Batches:(STRHB170001, STRHB170002 and STRHB170003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture,

		manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted.		
	Analytical method Validation study	Analytical method Validation study provided for both Drug substance and Drug product manufacturer.		
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Suntril Pharmaceuticals Pvt. Ltd Plot No 219, Phase I, HSIIDC, Alipur Barwala, Haryana India		
	API Lot No	Not provided		
	Description of Pack (Container closure system)	Paper foil for sachet packaging		
	Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
	Time Period	Real time: 6 months Accelerated: 6 months		
	Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	T-01	T-02	T-03
	Batch Size	5000 Sachet	5000 Sachet	5000 Sachet
	Manufacturing Date	08/21	08/21	08/21
	Date of Initiation			
	No. of Batches	03		
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No I/151-2Drug-I-2019/4138-Drug-I-7839 dated 22-10-2019 valid till 2 years. Issued by FDA , Haryana		
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided permission for import of API Strontium Ranelate (3000gm) vide letter No 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 From Assistant Director (I&E) DRAP , Lahore Documents/commercial invoice for procurement of Drug to be provided		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Summary data sheets and chromatograms are submitted		

	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided
3.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	3.2.S.4 The active substance specification includes tests for identity, LOD, related substances, heavy metals, pH, strontium content, particle size and assay. https://www.ema.europa.eu/en/documents/scientific-discussion/protelos-epar-scientific-discussion_en.pdf While quality parameters such as pH and particle size have not been performed neither by Drug substance nor Drug product manufacturer.
5.	3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture
6.	3.2.S.7 Submit stability data of Drug substance up to shelf life. Since already submitted (Real time) stability data was up to 9 months
7.	3.2.P.2.2.1 Pharmaceutical equivalence study and CDP to be provided against innovator/comparator product by performing all quality tests. Also Provide details of comparator product such as Exp. Date, Batch no. etc
8.	3.2.P.5 Justify selection criteria of chromatographic condition particularly wavelength i.e 239nm while Drug Substance manufacturer adjusted it as 306nm while analysing Drug substance.
9.	3.2.P.5 The specification for the finished product includes tests for characterization, average mass, uniformity of mass, pH, microbial quality, identification (organic part and strontium), assay (HPLC), degradation products, assay of strontium and dissolution. https://www.ema.europa.eu/en/documents/scientific-discussion/protelos-epar-scientific-discussion_en.pdf however, tests like pH ,microbial quality, assay of strontium and dissolution have not been performed by Drug Product manufacturer.
10.	3.2.P.8 Provide documents for the procurement of API with approval from DRAP. Also clarify Lot/Batch No of API that was imported.
11.	3.2.P.8 Provide Raw data sheets, and COA for both Real time and Accelerated stability data of all 3 batches. Moreover during stability study quality parameters such as pH ,microbial quality, assay of strontium and dissolution have not been assessed.

Decision: Deferred for submission of above mentioned shortcomings.

1011.	Name, address of Applicant / Marketing Authorization Holder	M/s Lawari International, Valley Road Gulkada, Saidu Sharif, Swat
	Name, address of Manufacturing site.	M/s Lawari International, Valley Road Gulkada, Saidu Sharif, Swat

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 26-10-2020 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29093 dated 13-10-2022
	Details of fee submitted	PKR 30,000/- Dated 15/03/2022
	The proposed proprietary name / brand name	Mefton Forte 500mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Mefenamic acid……..500mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	BP
	Proposed Pack size	1x20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mefenamic acid 500mg tablet MHRA approved
	For generic drugs (me-too status)	Postan Forte tablet 500mg M/s Pfizer Reg No 006978
	Name and address of API manufacturer.	M/s Ningbo Smart Pharmaceutical Co. Ltd No 1, Yi Cheng Road, Xiao, Beilun District , Ningbo, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility,

		physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(MFAR-2004400-J, MFAR-2004500-J and MFAR-2004600-J)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against Ponstan Forte 500mg tablet by Pfizer pharma. quality partameters compared were identification, assay, dissolution, uniformity of dosage, and impurities. Firm has submitted CDP results against the Ponstan Forte 500mg by Pfizer pharma in all three mediums i.e acidic medium (0.1NHCl), acetate buffer (Ph 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method Validation study	Firm has submitted analytical method Validation study reports for drug product as well as drug substance

STABILITY STUDY DATA	
Manufacturer of API	M/s Ningbo Smart Pharmaceutical Co. Ltd No 1, Yi Cheng Road, Xiao, Beilun District , Ningbo, China
API Lot No	MFAR-2006300-J
Description of Pack (Container closure system)	Alu-Alu blister with unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

	Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	T-01	T-02	T-03
	Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
	Manufacturing Date	10/21	10/21	10/21
	Date of Initiation	10-10-2021	10-10-2021	10-10-2021
	No. of Batches	03		
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided		

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by relevant Drug regulatory authority.
3.	2.3.P.6 Clarify specification of Drug Substance since DS manufacturer claimed specification of Mefenamic acid as BP while USP reference standard was provided
4.	3.2.S.4 Clarify analytical method of Drug Substance submitted by Drug Product manufacturer. Since it was not according to BP (as claimed by DS manufacturer) and submit analytical method verification studies accordingly
5.	3.2.P.2 Justify the quantity of drug mentioned in batch formula i.e 512.48/ tablet
6.	3.2.P.2.2.1 Provide details of reference product Ponstan Forte 500mg by Pfizer pharma (Exp. Date, Batch no. etc)
7.	3.2.P.5 Finished product specifications and analytical method provided is not according to BP (as claimed by firm). Justify the finished product specifications/analytical method provided by the firm and submit analytical validation studies of product accordingly.
8.	3.2.P.8 Provide documents for the procurement of API with approval from DRAP.
9.	3.2.P.8 Provide raw data sheets of stability data (both accelerated and real time) containing results /calculations of assay. Also clarify the reference of quality parameters/ specifications tested during stability study.

Decision: Deferred for submission of above mentioned shortcomings.

1012.	Name, address of Applicant / Marketing Authorization Holder	M/s News Pharma, Plot No 42, Sunder Industrial Estate, Lahore

	Name, address of Manufacturing site.	M/s News Pharma, Plot No 42, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided copy of GMP certificate No 146/2018-DRAP (AD-612094-790) dated 28-08.2018 based on inspection dated 26.04.2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of approval letter for issuance of DML dated 18.02.2023 wherein Liquid injection (General) was mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29638 dated 19-10-2022
	Details of fee submitted	PKR 30,000/- Dated 19/09/2022
	The proposed proprietary name / brand name	New-Set 8mg/4ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ondansetron HCl eq. to Ondansetron…....8mg
	Pharmacotherapeutic Group of (API)	5HT3 Antagonist
	Pharmaceutical form of applied drug	Liquid injection
	Reference to Finished product specifications	USP
	Proposed Pack size	5’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 8mg/4ml injection by Novartis MHRA approved
	For generic drugs (me-too status)	Vemtix 8mg/4ml injection Reg No 093252 by M/s Biolab Islamabad
	Name and address of API manufacturer.	M/s Anugraha Chemicals research and development manufacture and supply of API, Intermediate and Fine chemicals. D-47 to D-50, C-62&C-63, KSSIDC , Industrial Estate Banglre India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.		
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6months Batches: 17002, 17003 and 17004		
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study was performed against Zofran Injection (GSK pharma). Quality parameters compared were identification, Ph, assay, uniformity of dosage, particulate matter, BET and sterility test.		
	Analytical method Validation study	Analytical method Validation study of Drug product was provided.		
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Anugraha Chemicals research and development manufacture and supply of API, Intermediate and Fine chemicals. D-47 to D-50, C-62&C-63, KSSIDC , Industrial Estate Banglre India		
	API Lot No	AOND-22006		
	Description of Pack (Container closure system)	USP type I, glass ampoule		
	Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
	Time Period	Real time: 6 months Accelerated: 6 months		
	Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	T-01	T-02	T-03
	Batch Size	500 ampoules	500 ampoules	500 ampoules
	Manufacturing Date	11/21	11/21	11/21
	Date of Initiation	02-11-2021	02-11-2021	02-11-2021
	No. of Batches	03		

	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till1 year. Issued by DCA, Karnataka
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of commercial invoice dated 14.10.2021 wherein 15 g ondansetron HCl (injection grade) was mentioned Batch No AOND-22006 Approval from DRAP (I&E) is required
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	Firm again provided copy of GMP certificate No 146/2018-DRAP (AD-612094-790) dated 28-08.2018 based on inspection dated 26.04.2018	Updated GMP status is required
2.	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Firm has provided copy of GMP certificate No DD011S220000011dated 31.01.2024 valid till1 year. Issued by DCA, Karnataka	
3.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	
4.	3.2.S.4 The acceptance criteria for quality tests such as Residue on ignition, chloride and water content is not as per USP. Clarify it	CoA of Drug substance has been revised as per USP	
5.	3.2.S.4 Provide analytical verification study performed by Drug Product manufacturer.	Provided	
6.	3.2.S.4 Provide results of analysis of relevant batch (AOND-22006)	CoA of relevant batch (AOND-22006) has been	

	of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture	provided by both Drug substance and Drug product manufacturers	
7.	3.2.P.2.2.1 Provide details of comparator product such as Exp. Date, Batch no. etc against which Pharmaceutical equivalence study was performed.	Provided as follows: Zofran Injection (GSK pharma). Batch No: T0720 Mfg date: 10-2021 Exp date: 09-2023	
8.	3.2.P.2. The quantity of excipients as provided in reference product (MHRA approved) by JCSH Pharma Ltd is 14.4 mg of sodium as sodium chloride and sodium citrate. Justify the quantities of sodium chloride and sodium citrate mentioned in Batch formula.	*14.4 mg sodium is produced from 36 mg of sodium chloride whereas sodium citrate is used only for Ph adjustment*.	Justified
9.	3.2.P.8 Provide documents for the procurement of API with approval from DRAP.	*API was directly received through DHL, slip attached dated 15.10.2021*	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1013.	Name, address of Applicant / Marketing Authorization Holder	M/s Lawari International, Valley Road Gulkada, Saidu Sharif, Swat
	Name, address of Manufacturing site.	M/s Lawari International, Valley Road Gulkada, Saidu Sharif, Swat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 26-10-2020 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 28255 dated 05-10-2022
	Details of fee submitted	PKR 30,000/- Dated 15/03/2022
	The proposed proprietary name / brand name	Pregab 75mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin……..75mg
	Pharmacotherapeutic Group of (API)	Anti convulsants
	Pharmaceutical form of applied drug	Hard Gelatin Capsule
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica Capsule 75mg M/s Pfizer USFDA approved
	For generic drugs (me-too status)	Zeegap capsule 75mg By M/s Hilton pharma Karachi Reg No 047359
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical company Ltd Chuannan , Duqiao, Linhai, Zhejiang , 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches:(D5248-14-002, D5248-14-003 and D5248-14-004)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has not been performed Firm has submitted CDP results against the Lyrica 75mg capsule by Upjohn UK Ltd in Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method Validation study	Firm has submitted analytical method Validation study reports for drug product as well as drug substance

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical company Ltd Chuannan , Duqiao, Linhai, Zhejiang , 317016, China		
API Lot No	D5248-19-069		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	06/21	06/21	06/21
Date of Initiation	08-06-2021	08-06-2021	08-06-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		

	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by relevant drug regulatory authority.
3.	3.2.P.2.2.1 Submit Pharmaceutical Equivalence study against reference product i.e Lyrica 75mg capsule by Upjohn UK Ltd. Also provide details of reference product (Exp. Date, Batch no. etc)
4.	3.2.P.2.2.1 Perform CDP against all three mediums (pH 1.2, 4.5 and 6.8) and submit results accordingly. As firm provided results of CDP performed in phosphate buffer (Ph 6.8) only.
5.	3.2.P.5 Justification to be provided for selection of dissolution parameters i.e dissolution medium (0.06 N HCl and volume of dissolution medium (900ml) etc since dissolution parameters mentioned in "USFDA guidance document on Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" recommends dissolution medium as "500 mL of 0.1N HCl in aqueous medium"), acceptance criteria NLT 80% in 30 min.
6.	3.2.P.8 Provide documents for the procurement of API with approval from DRAP.
7.	3.2.P.8 Provide raw data sheets of stability data (both accelerated and real time) containing results /calculations of dissolution and assay.

Decision: Deferred for submission of above mentioned shortcomings.

1014	Name, address of Applicant / Marketing Authorization Holder	M/s Jenner Pharmaceuticals Pvt Ltd, Plot No 2, M-2 Pharma zone, 28th KM Lahore, Sharaqpur road, Dist Sheikhupura
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals Pvt Ltd, Plot No 2, M-2 Pharma zone, 28th KM Lahore, Sharaqpur road, Dist Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 07-08-2015 specifying Tablet (General) section..
	Status of application	☒ New Drug Product (NDP)

		☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 30581 dated 30-10-2022
	Details of fee submitted	PKR 30,000/- Dated 01/10/2022
	The proposed proprietary name / brand name	Jensolor 2mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride (as succinate) ……..2mg
	Pharmacotherapeutic Group of (API)	Gastroprokinetic agent Selective serotonin (5HT4) agonist
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	10's, 14's and 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Resolor 2mg tablet Takeda UK Ltd MHRA approved
	For generic drugs (me-too status)	Pru-cic Tablet 2mg By M/s Searle Karachi Reg No 116036
	Name and address of API manufacturer.	M/s Kimia Biosciences Ltd, Village Bhondsi, Tehsil Sohna, Distirct-Gurgaon 122102 Haryana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has not been performed Firm has submitted CDP results against the Resolor tablet 2mg by Takeda pharma, Japan (Batch No LBL7N00) in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method Validation study	Firm has submitted analytical method Validation study reports for drug product as well as drug substance		
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Kimia Biosciences Ltd, Village Bhondsi, Tehsil Sohna, Distirct-Gurgaon 122102 Haryana, India		
	API Lot No	KB/PPD/SPP/21/003		
	Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
	Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
	Time Period	Real time: 6 months Accelerated: 6 months		
	Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	JSL-PB-036001	JSL-PB-036002	JSL-PB-036003
	Batch Size	1000 tab	1000 tab	1000 tab
	Manufacturing Date	03/22	03/22	03/22
	Date of Initiation	03/24	03/24	03/24
	No. of Batches	03 n		
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 4138-Drug-2019/8359 dated 18-11-2019 valid till 17-11-2022 issued by FDA , Haryana		
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No KBLEXP/21-22/074 dated 13/12/2021 Mentioning API Prucalopride succinate 32gm Batch No KB/PPD/SPP/21/003, Cleared by DRAP (I&E) dated 14-01-2022		

	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Firm has taken the dissolution specification from FDA assessment report of innovator "Motegrity tablet" NDA 210166 which specify following dissolution parameters:

Apparatus	USP Apparatus 2 (Paddle)
Speed	50 rpm
Dissolution media	0.1 N Hydrochloric Acid
Volume	900 mL
Time	10, 20, 30, and 45 min
Temperature	37 ± 0.5 °C
Specifications	NL 80% (Q) in 20 minutes

Firm took above mentioned specification and tested accordingly from initial stage to onward.

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	Firm has provided updated GMP status i.e GMP certificate based on inspection dated 04.06.2022 valid till three years.	Complied
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by relevant Drug regulatory authority .	Firm has provided copy of GMP certificate No 4138-Drug-2022/6790 dated 07-09-2022 valid till 17-11-2022 issued by FDA, Haryana Valid till two years from the date of issue.	Complied
3.	3.2.S.7 Provide stability data of Drug Substance (both Accelerated and Real time) of 3 batches.	Stability study has been provided of following conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(LA-PPD-SF-18-001, LA-PPD-SF-18-002 and LA-PPD-SF-18-003)	Complied
4.	3.2.P.2.2.1 Submit Pharmaceutical Equivalence study against reference product i.e Resolor tablet 2mg by Janssen Italy (Batch No LBL7N00). Also provide details of reference product (Exp. date)	Firm has submitted Pharmaceutical Equivalence study report against the Resolor tablet 2mg by Takeda pharma, Japan (Batch No LBL7N00). Quality parameters	Complied

		comparted were DT, Avg weight, LOD, Dissolution and Assay.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Registration applications of New DML (Human):

1015.	Name, address of Applicant / Marketing Authorization Holder	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Name, address of Manufacturing site.	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection for grant of DML was conducted on 12.04.2023
	Evidence of approval of manufacturing facility	Liquid Ampoule (General), approval and granted by DRAP (Central Licensing Board) vide letter No. F. 2-7/2017-Lic, dated: 18-10-2023.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID 49R-9XV-GBVH dated 21-02-2024
	Details of fee submitted	Rs. 30,000/- dated 22-01-2024 Fee submitted for 40mg Artemether injection instead of 80mg injection
	The proposed proprietary name / brand name	Almether injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Artemether……80mg
	Pharmacotherapeutic Group of (API)	Anti-malarial

	Pharmaceutical form of applied drug	Injection
	Reference to Finished product specifications	Int.Ph Specification
	Proposed Pack size	1mlx6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Artemether injection WHO approved
	For generic drugs (me-too status)	Arthenate injection 80mg By city pharmaceutical laboratories
	Name and address of API manufacturer.	Calyx Chemical and Pharmaceuticals Ltd Plot No N/102,91,90 M.I.D.C, Boisar, Tarapur , Dist-Thane ZONE 4
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 48 months MO/ARM/0901, MO/ARM/0902, MO/ARM/0903
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	Calyx Chemical and Pharmaceuticals Ltd Plot No N/102,91,90 M.I.D.C, Boisar, Tarapur , Dist-Thane ZONE 4	
API Lot No.	AM4N/20210716	

Description of Pack (Container closure system)	Type I glass ampoule		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ART-TB-001	ART-TB-002	ART-TB-003
Batch Size	3000 ampoules	3000 ampoules	3000 ampoules
Manufacturing Date	05-2023	05-2023	05-2023
Date of initiation	22/05/2023	22/05/2023	22/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of certificate No: 610079 valid till 18.07.2022 issued by FDA Maharashtra state.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice No Exp-078/T dated 28.02.2022 is provided wherein 10kg Artemether (Batch No AM4N/20210716) in the name of M/s Newton Healthcare Pvt Ltd, Karachi. Approved by I&E DRAP is required.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:
Fee submitted for 40mg Artemether injection instead of 80mg injection as verified from online database (https://e.dra.gov.pk/)
a) 2.3.P.6 COA of primary / secondary reference standard including source and lot number to be provided.
b) 3.2.S.2.1: Clarify API/DS manufacturer, whether Micro Orgo Chem, Gujrat India or Calyx Chemical and Pharmaceuticals Ltd. Since procurement documents and CoA bearing name i.e Calyx Chemical and Pharmaceuticals Ltd while analytical method validation study report and stability data bearing name of manufacturer as Micro Orgo Chem, Gujrat India
c) 3.2.S.4 Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.
d) 3.2.S.7 Stability data of 3 batches at accelerated and real time conditions (as per zone IV-A)
e) 3.2.P.2 Provide details of container closure system (Glass ampoule) such as glass type and suitability testing/Quality testing (as per relevant pharmacopeia) to be submitted

f) 3.2.P.2.2.1 Provide Pharmaceutical equivalence study and details of comparator/Reference product such as Exp. Date, Batch no. etc against which Pharmaceutical equivalence study was performed.

g) 3.2.P.8 Provide loan agreement for borrowing API from M/s Newton Healthcare Pvt Ltd, Karachi. Moreover approval from I&E DRAP is required.

Reply:

COA of primary / secondary reference standard including source and lot number is provided. API/DS manufacturer is Calyx Chemical and Pharmaceuticals Ltd, as clarified by the firm. Summary of Analytical method verification study of Drug Substance performed by Drug Product manufacturer, has been provided. Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months MO/ARM/0901, MO/ARM/0902, MO/ARM/0903 Firm provided protocol/SOP for testing glass vial/ampoule (USP type I). Firm has provided pharmaceutical equivalence study report against comparator product Arthenate injection 80mg/ml by City Pharmaceutical Lab (Batch No I-071) quality parameters compared were appearance, Ph and assay Loan agreement for borrowing API (2kg) from M/s Newton Healthcare Pvt Ltd, Karachi. However, approval from I&E DRAP/clearance certificate is required for procurement of API.
Remarks: Name of manufacturer mentioned on procurement documents and CoA of Drug substance as Calyx Chemical and Pharmaceuticals Ltd while analytical method validation study report and stability data bearing name of Micro Orgo Chem, Gujrat India. Status of Micro Orgo Chem, Gujrat India yet to be clarified Suitability testing/Quality testing (as per relevant pharmacopeia) yet to be provided Approval of Procurement documents i.e Commercial Invoice No Exp-078/T dated 28.02.2022 (in the name of M/s Newton Healthcare Pvt Ltd, Karachi) by I&E, DRAP to be provided. Fee submitted for 40mg Artemether injection instead of 80mg injection as verified from online database (https://e.dra.gov.pk/)
Decision: Deferred for following requirements: **a) Status of Micro Orgo Chem, Gujrat India to be clarified since name mentioned on development data (analytical method validation study report and stability data) as Micro Orgo Chem, Gujrat India.** **b) Provide suitability testing/Quality testing (as per USP) to be submitted.** **c) Approval of Procurement documents by I&E, DRAP to be provided.**

1016	Name, address of Applicant / Marketing Authorization Holder	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Name, address of Manufacturing site.	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection for grant of DML was conducted on 12.04.2023
	Evidence of approval of manufacturing facility	Eye ointment (General), approval and granted by DRAP (Central Licensing Board) vide letter No. F. 2-7/2017-Lic, dated: 18-10-2023.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID 55A-4JN-EPWTdated 27-03-2024

	Details of fee submitted	Rs.30,000/- dated 22-01-2024
	The proposed proprietary name / brand name	Alcipro Eye ointment 0.3%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Ciprofloxacin HCl eq. to Ciprofloxacin……3mg
	Pharmacotherapeutic Group of (API)	antibacterial agent
	Pharmaceutical form of applied drug	Ophthalmic ointment
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	3.5gmx1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciloxan Eye ointment Novartis pharma switzerland
	For generic drugs (me-too status)	Rocip Eye ointment Regn No.031297 Manufacturer: Remington Pharmaceutical Industries Pvt Ltd
	Name and address of API manufacturer.	Zenith Chemical Industries Pvt Ltd, 16km off Ferozepur road behind wapda grid station
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months ZCFX12-001, ZCFX12-002 and ZCFX12-003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Rocip Eye ointment by Remington (Batch No DK003, Exp date 01-2026). Quality parameters such as appearance and assay against Test product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zenith Chemical Industries Pvt Ltd, 16km off Ferozepur road behind wapda grid station		
API Lot No.	ZCFX21-015		
Description of Pack (Container closure system)	Collapsible tube (3.5g)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-TB-01EO	CP-TB-02EO	CP-TB-03EO
Batch Size	1000 tubes	1000 tubes	1000 tubes
Manufacturing Date	05-2023	05-2023	05-2023
Date of initiation	04/05/2023	04/05/2023	04/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate dated 24.09.2021 based on inspection dated 14.07.2021 valid two years issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable Delivery challan dated 16.09.2022 has been provided wherein 25kg ciprofloxacin HCl is mentioned purchased by M/s Newton Health care (Pvt) Ltd. Loan agreement to be provided regarding purchase of API
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:
Provide updated GMP certificate of API manufacturer issued by DRAP
2.3.P.6 COA of primary / secondary reference standard including source and lot number to be provided.
3.2.S.4 Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.

3.2.P.7 Provide details of container closure system such as materials of construction, unit count or fill size, container size to be submitted. 3.2.P.8 Provide loan agreement for borrowing API from M/s Newton Health care (Pvt) Ltd.
Reply: Firm again submitted copy of GMP certificate dated 24.09.2021 based on inspection dated 14.07.2021 valid two years issued by DRAP COA of primary / secondary reference standard including source and lot number is provided Analytical method validation study was performed for solvents such as methanol, ethanol, toluene and benzene instead of Drug substance i.e ciprofloxacin. Details of container closure system have been provided however fill weight of tube yet to be provided. Loan agreement for borrowing API (2kg) from M/s Newton Healthcare Pvt Ltd, Karachi. However, approval from I&E DRAP/clearance certificate is required for procurement of API.
Decision: Approved. • **Before issuance of registration letter firm will provide following documents:** **a) Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.** **b) Documents for procurement of API approved from I&E DRAP** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1017.	Name, address of Applicant / Marketing Authorization Holder	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Name, address of Manufacturing site.	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection for grant of DML was conducted on 12.04.2023
	Evidence of approval of manufacturing facility	Liquid Injectable vial SVP (General), approval and granted by DRAP (Central Licensing Board) vide letter No. F. 2-7/2017-Lic, dated: 18-10-2023.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID 61S-5N1-1JHRdated 06-03-2024
	Details of fee submitted	Rs.30,000/- dated 02-12-2023
	The proposed proprietary name / brand name	Falzol Infusion 500mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Metronidazole……500mg

	Pharmacotherapeutic Group of (API)	Imidazole antibacterial agent
	Pharmaceutical form of applied drug	Solution for infusion
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	100mlx1's Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	metronidazole 5mg/ml MHRA approved
	For generic drugs (me-too status)	Flagyl Infusion 500mg/100ml Regn No.005102 Manufacturer: Sanofi-Aventis Pakistan Limited.
	Name and address of API manufacturer.	Hubei Hong Yuan Pharmaceutical Technology Co., Ltd 1.No 126 Dabieshan Road, Industrial and Economic Development Zone Luotian country Huanggang city, Hubei province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months 070101, 070102, 070103
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	Hubei Hong Yuan Pharmaceutical Technology Co., Ltd 1.No 126 Dabieshan Road, Industrial and Economic Development Zone Luotian country Huanggang city, Hubei province China.		
API Lot No.	0182301200		
Description of Pack (Container closure system)	100ml glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MD-TB-001	MD-TB-002	MD-TB-003
Batch Size	300 vials	300 vials	300 vials
Manufacturing Date	05-2023	05-2023	05-2023
Date of initiation	09/05/2023	09/05/2023	09/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No: HB20180424 dated 31.07.2018 valid till 30.07.2023 issued by China Food and Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of clearance certificate dated 08.03.2023 wherein metronidazole (500kg) Batch No 0182301200 was mentioned, in the name of M/s Ophth pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:
2.3.P.6 COA of primary / secondary reference standard including source and lot number to be provided.
3.2.S.4 Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.
3.2.P.2 Provide details of container closure system (Glass vial) such as glass type and suitability testing/Quality testing (as per relevant pharmacopeia) to be submitted.

3.2.P.2.2.1 Provide Pharmaceutical equivalence study and details of comparator/Reference product such as Exp. Date, Batch no. etc against which Pharmaceutical equivalence study was performed.

3.2.P.5: Clarify assay method (along with chromatographic conditions) of finished product adopted by product manufacturer since same assay method (HPLC) has not been found in BP.
3.2.P.8 Provide loan agreement for borrowing API from M/s M/s Ophth pharma (Pvt) Ltd.

Reply:
COA of primary / secondary reference standard including source and lot number is provided.
Summary of Analytical method verification study of Drug Substance performed by Drug Product manufacturer has been provided.

Firm provided protocol/SOP for testing glass vial/ampoule (USP type I) Firm has provided pharmaceutical equivalence study report against comparator product Flagyl infusion 500mg/100ml by Snofi Aventis Pakistan Limited (Batch No AL1012) quality parameters compared were appearance, Ph and assay Assay method for metronidazole infusion is spectrophotometric in BP 2022 while HPLC method is adopted as HPLC from USP monograph. I think HPLC method is more efficient method. Loan agreement for borrowing API (2kg) from M/s OPHTH pharma Pvt Ltd, Karachi.
Remarks: Firm claimed BP specification, all quality parameters/acceptance limit were as per BP However assay method adopted as per USP (i.e HPLC). Suitability testing/Quality testing (as per relevant pharmacopeia) yet to be provided.
Decision: Approved. • **Before issuance of registration letter firm will submit analytical testing method of product as per BP along with performance report.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1018.	Name, address of Applicant / Marketing Authorization Holder	M/s Abbott Laboratories Pakistan Ltd, opposite Radio Pakistan Transmission centre Hyderabad Road Karachi
	Name, address of Manufacturing site.	M/s Abbott Laboratories Pakistan Ltd, opposite Radio Pakistan Transmission centre Hyderabad Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate based on Inspection dated 09.03.2023 valid till two years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 15-06-2021 specifying Tablet (General) section..
	Status of application	☒ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13177 dated 29-05-2023
	Details of fee submitted	PKR 30,000/- Dated 31/01/2023
	The proposed proprietary name / brand name	Equasis Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Vildagliptin……..50mg
	Pharmacotherapeutic Group of (API)	Anti hyperglycemic agent
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	Not provided
	Proposed Pack size	10’s , 28’s
	Proposed unit price	As per DPC

	The status in reference regulatory authorities	Galvus 50mg tablet by M/s Novartis Pharmaceutical UK Ltd MHRA Approved
	For generic drugs (me-too status)	Galvus 50mg tablet by M/s Novartis, Reg No 059038
	Name and address of API manufacturer.	M/s Lee Pharma Limited Survey No 30P, 31P,32P, 34P & 35P, Plot No 22A and 22B Denotified area-APSEZ, Lalam Koduru Village, Rambilli Mandal, Visakhapatnam District, Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (VNFP17001, VNFP17002 and VNFP17003) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Galvus 50mg tablet by M/s Novartis Farmaceutica S.A Spain M.A Holder in Pakistan : Novartis Pharma Pakistan Limited Batch No BWY 84 Quality parameters such as Appearance, uniformity of dosage, water by KF, identification, disintegration time, dissolution assay, and related substances against Test product (Batch No 422004XZ)

		Firm has submitted CDP results of their product against the same innovator product Galvus 50mg tablet by M/s Novartis Farmaceutica S.A Spain in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was not required since more than 85% drug release within 15 min.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Lee Pharma Limited Survey No 30P, 31P,32P, 34P & 35P, Plot No 22A and 22B Denotified area-APSEZ, Lalam Koduru Village, Rambilli Mandal, Visakhapatnam District, Andhra Pradesh, India		
API Lot No..Batch number	VNFP22013U4		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	422004XV	422005XV	422006XV
Batch Size	---	---	----
Manufacturing Date	06/22	06/22	06/22
Date of Initiation	18.07.2022	18.07.2022	18.07.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations

1.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided
2.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. Moreover, clarify stability batch size.
3.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.
4.	3.2.P.5 Finished product specification to be mentioned on Form5F along with prescribed fee.
5.	3.2.P.5 Analytical Method Validation studies was performed by Abbott HealthCare Pvt Ltd, Mumbai, although method has been test method has been transferred from Abbott HealthCare Pvt Ltd, Mumbai to Abbott Karachi Pakistan yet validation studies to be performed at manufacturing site.
6.	3.2.P.8 Provide document for procurement of API with Clearance from DRAP.

Decision 330th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings

Reply:

Sr.#	Observations	Reply	Remarks
1.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Firm has provided copy of GMP certificate No E-2083809/dd/dca/vsp/2023 issued by DCA Andhra Pradesh valid till 21-06-2024	Complied
2.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. Moreover, clarify stability batch size.	Batch Manufacturing Record (BMR) for all the batches (100,000 tab) of drug product for which stability studies data is provided .	Complied
3.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Method used for analysis of API from Finished Product Manufacturer has been provided API test method yet to be validated in QC laboratory. We ensure to complete this activity before commercial batch release activities for subject product.	Analytical method validation studies of Drug substance yet to be provided
4.	3.2.P.5 Finished product specification to be mentioned on Form5F along with prescribed fee.	Fee of Rs. 7500/- is provided dated for finished product specification to be mentioned on Form5F as “as per innovator specification”	Complied
5.	3.2.P.5 Analytical Method Validation studies was performed by Abbott	The R&D Lab in Abbott Pakistan has tested the	Analytical Method Validation studies of

	HealthCare Pvt Ltd, Mumbai, although method has been test method has been transferred from Abbott HealthCare Pvt Ltd, Mumbai to Abbott Karachi Pakistan yet validation studies to be performed at manufacturing site.	Registration Batches following test method transfer activity, which were assessed to be simple in nature hence test method transfer approach is sufficient at this stage. We ensure to carry out this activity at the time of commercial batch manufacturing and QC testing.	Drug Product to be carried out at manufacturing site i.e Abbott Karachi Pakistan
6.	3.2.P.8 Provide document for procurement of API with Clearance from DRAP.	Firm has provided commercial invoice (No 4017/LP/2021-22) dated 28.02.2022 for Vildagliptin batch No VNFP22013U4 (65Kg) cleared by DRAP (I&E) Karachi 06.01.2022	Complied
7.	3.2.P.8 Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) to be provided.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 9 months	Complied

Decision 331st meeting: Deferred for following reasons:
API test method to be validated at product manufacturing site i.e M/s Abbott Laboratories Pakistan Ltd, Hyderabad Road Karachi.
Analytical Method Validation studies of Drug Product to be carried out at manufacturing site i.e M/s Abbott Laboratories Pakistan Ltd, Hyderabad Road Karachi.

Reply: Firm has provided Analytical Method Validation studies of Drug Product carried out at manufacturing site i.e M/s Abbott Laboratories Pakistan Ltd, Hyderabad Road Karachi. However Analytical Method Validation studies of API will be submitted shortly

Decision: Approved.

- **Before issuance of registration letter firm will submit analytical method validation study of API carried out by finished product manufacturer at manufacturing site i.e M/s Abbott Laboratories Pakistan Ltd, Hyderabad Road Karachi**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Routine cases:

1019.	Name, address of Applicant / Marketing Authorization Holder	M/s Welmark Pharmaceuticals, Plot No. 122, Block B, Phase V, Industrial Estate , Hattar.
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals, Plot No. 122, Block B, Phase V, Industrial Estate , Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 34694: 30-11-2022

	Details of fee submitted	PKR 30,000/- : 29-11-2022
	The proposed proprietary name / brand name	Nitren 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each un coated tablet contains: Nebivolol as HCl…2.5mg
	Pharmacotherapeutic Group of (API)	Highly selective beta blocker
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Nebivolol 2.5mg Tablet (MHRA Approved)
	For generic drugs (me-too status)	Nibovo Tablet 2.5mg by Dyson Pharmaceutical Reg No 078846
	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer.	Firm again submitted copy of GMP certificate of the firm based on inspection dated 11-11-2021.	Updated GMP status is required.
2.	Provide updated GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided copy of GMP certificate No 22073413 valid till 03/07/2024 issued by Food and Drug Control Administration, Gujrat	
3.	Provide analytical method validation studies of Drug substance from Drug product manufacturer.	Provided	
4.	The product specification includes tests for appearance, identity, assay, related substances, dissolution, uniformity of dosage units, average weight, water content, hardness, friability, breakability, microbial quality As per public assessment report of CBG-MEB (Netherland Medicine Evaluation Board). However, tests like "related substances" and "water content" has not been performed/controlled.	Firm has provided revised finished product specification however water content test has not been mentioned	Water content test to be included in finished product specification along with performance report Along with fee
5.	Justify selection of wavelength (ʎ max) for assay of Drug Product i.e 281nm while Drug substance manufacturer adopted analytical wavelength (ʎ max) as 220nm.	Firm has submitted revised method of analysis wherein ʎ max is mentioned as 220nm.	Fee is required
6.	Perform Analytical method validation study of Drug Product (including linearity and robustness).	Provided	
7.	Provide documents for the procurement of API (21NB0001)with approval from DRAP.	Only license to import is provided	

Decision: Approved.

- **Before issuance of registration letter firm will submit fee of Rs 7500/- on account of pre-registration variation as per S.R.O 496(I)12023 dated 17th April, 2023**
- **Before issuance of registration firm will perform water content test and report will be submitted accordingly.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1020.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 31996: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 28.09.2022
	The proposed proprietary name / brand name	Sacuvex 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex) ……..….24mg Valsartan (as sacubitril valsartan sodium salt complex) …….. 26mg
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Ubutril Tablet 50mg by Weather folds pharmaceuticals 105351
	Proposed unit price	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
1.	Submit updated GMP status of finished product manufacturer.	Firm has submitted copy of GMP certificate of the firm based on inspection dated 03-04-2023.	
2.	Perform Analytical method validation study of Drug Substance (Sacubitril / Valsartan sodium salt complex) by Drug product manufacturer	Provided	
3.	Submit Analytical method for testing Drug substance **(**Sacubitril / Valsartan sodium salt complex).	Provided	

4.	Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	Provided Batch No RD-LCZ696-202104291	
5.	Clarify the Percentage of sacubitril and valsartan mentioned under batch formula as 42.95% (sacubitril) and 45.46% (valsartan) while assay limit of both ingredients as per CoA is: 47.1%-49.6% (sacubitril) 49.8%-52.4% (valsartan)	Potency adjustment was done due to salt factor (i.e 1.132)	Clarified
6.	Provide complete CDP report wherein % drug release (both ingredients) to be provided in each sampling point (all three mediums) of both test and reference products. Also provide pharmaceutical equivalence study against reference/comparator product.	f1 and f2 values haven calculated for both API however detailed release profile at each time point has been provided for valsartan only.	Provide complete CDP report wherein % drug release (sacubitril) to be provided in each sampling point (all three mediums) of both test and reference products.
7.	Quality parameters like uniformity of dosage unit and microbial purity have not been tested/ controlled.	Provided	
8.	Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided	
9.	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing and Record of Digital data logger	Provided	

Decision: Approved.

- **Before issuance of registration letter firm will provide complete CDP report wherein % drug release (sacubitril) will be provided in each sampling point (all three mediums) of both test and reference products.**
- **Before issuance of registration firm will provide Pharmaceutical equivalence study against reference/comparator product.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1021.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No & date of submission	Form 5F: Dy. No. 32001: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 28.09.2022
	The proposed proprietary name / brand name	Sacuvex 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex) ……..….49mg Valsartan (as sacubitril valsartan sodium salt complex) ……..51mg
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Ubutril Tablet 100mg by Weather folds pharmaceuticals 105352
	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
1.	Submit updated GMP status of finished product manufacturer.	Firm has submitted copy of GMP certificate of the firm based on inspection dated 03-04-2023.	
2.	Perform Analytical method validation study of Drug Substance (Sacubitril / Valsartan sodium salt complex) by Drug product manufacturer	Provided	
3.	Submit Analytical method for testing Drug substance **(**Sacubitril / Valsartan sodium salt complex).	Provided	
4.	Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	Provided Batch No RD-LCZ696-202104291	
5.	Clarify the Percentage of sacubitril and valsartan mentioned under batch formula as 42.95% (sacubitril) and 45.46% (valsartan) while assay limit of both ingredients as per CoA is: 47.1%-49.6% (sacubitril) 49.8%-52.4% (valsartan)	Potency adjustment was done due to salt factor (i.e 1.132)	Clarified

6.	Provide complete CDP report wherein % drug release (both ingredients) to be provided in each sampling point (all three mediums) of both test and reference products. Also provide pharmaceutical equivalence study against reference/comparator product.	Provided	However pharmaceutical equivalence study against reference/comparator product yet to be provided
7.	Quality parameters like uniformity of dosage unit and microbial purity have not been tested/ controlled.	Provided	
8.	Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided	
9.	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing and Record of Digital data logger	Provided	

Decision: Approved.

- **Before issuance of registration letter firm will provide Pharmaceutical equivalence study against reference/comparator product.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1022.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 31997: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 30.09.2022
	The proposed proprietary name / brand name	Sacuvex 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex) ……..….97mg Valsartan (as sacubitril valsartan sodium salt complex) ……..103mg
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	MHRA Approved

	For generic drugs (me-too status)	Ubutril Tablet 200mg by Weather folds pharmaceuticals 105353
	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
1.	Submit updated GMP status of finished product manufacturer.	Firm has submitted copy of GMP certificate of the firm based on inspection dated 03-04-2023.	
2.	Perform Analytical method validation study of Drug Substance (Sacubitril / Valsartan sodium salt complex) by Drug product manufacturer	Provided	
3.	Submit Analytical method for testing Drug substance **(**Sacubitril / Valsartan sodium salt complex).	Provided	
4.	Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	Provided Batch No RD-LCZ696-202104291	
5.	Clarify the Percentage of sacubitril and valsartan mentioned under batch formula as 42.95% (sacubitril) and 45.46% (valsartan) while assay limit of both ingredients as per CoA is: 47.1%-49.6% (sacubitril) 49.8%-52.4% (valsartan)	Potency adjustment was done due to salt factor (i.e 1.132)	Clarified
6.	Provide complete CDP report wherein % drug release (both ingredients) to be provided in each sampling point (all three mediums) of both test and reference products. Also provide pharmaceutical equivalence study against reference/comparator product.	Provided	However pharmaceutical equivalence study against reference/comparator product yet to be provided
7.	Quality parameters like uniformity of dosage unit and microbial purity have not been tested/ controlled.	Provided	
8.	Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided	
9.	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing and Record of Digital data logger	Provided	

Decision: Approved.

- **Before issuance of registration letter firm will provide Pharmaceutical equivalence study against reference/comparator product.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1023.	Name, address of Applicant / Marketing Authorization Holder	M/s Aulton Pharmaceuticals , Plot No 84/I, Block-A , Phase 5, industrial estate Hattar (KPK) , Pakistan.
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals , Plot No 84/I, Block-A , Phase 5, industrial estate Hattar (KPK) , Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 1970: 20-01-2023
	Details of fee submitted	PKR 30,000/- : 17-01-2023
	The proposed proprietary name / brand name	Prazan 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 10mg by Searle Pharmaceutical
	Proposed pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer.	Application for GMP inspection has been submitted and R&I copy (dated 22.01.2024) is attached with application Last inspection report conducted in 2020 is also attached	
	Perform Analytical method validation study of Drug Product (including linearity, intermediate precision and robustness). Moreover, results of specificity parameter has not been performed.	Analytical method validation study of Drug Product (including linearity, intermediate precision and robustness) is provided	However results of specificity parameter has not been submitted yet.
	Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate	Firm has provided the comparative dissolution of the product in all three medias as per ICH	

	buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution medium used by the firm is 0.1NHCl (pH 1.2) with 50 rpm. using USP type II apparatus. Justification to be provided for selection of dissolution medium	guidelines i.e 0.1NHCl , acetate buffer pH 4.5 and phosphate pH 6.8. The dissolution profile of product in 0.1NHCl and acetate buffer pH 4.5 is equal.	
	Justify selection of wavelength (ʎ max) for assay of Drug Product while Drug substance manufacturer adopted analytical wavelength (ʎ max) as 230nm	The raw material was tested using same method as of API manufacturer and detection wavelength of 230nm was used Analytical method for Drug product was developed and validated. While optimization of analytical method for Drug product the UV spectra was observed and maximum absorbance was found to be at 254nm, so this wavelength was used. The method was validated as per ICH guidelines and USP	

Decision: Approved.

- **Before issuance of registration letter firm will submit revised dissolution method in line with innovator i.e USFDA approved formulation VOQUEZNA and results of specificity parameter of Analytical method validation study of Drug Product.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1024.	Name, address of Applicant / Marketing Authorization Holder	M/s Aulton Pharmaceuticals , Plot No 84/I, Block-A , Phase 5, industrial estate Hattar (KPK) , Pakistan.
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals , Plot No 84/I, Block-A , Phase 5, industrial estate Hattar (KPK) , Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 1852: 19-01-2023
	Details of fee submitted	PKR 30,000/- : invalid date
	The proposed proprietary name / brand name	Prazan 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker

	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Voniza Tablet 20mg by M/s Hilton Pharmaceutical
	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer.	Application for GMP inspection has been submitted and R&I copy (dated 22.01.2024) is attached with application Last inspection report conducted in 2020 is also attached	
	Perform Analytical method validation study of Drug Product (including linearity, intermediate precision and robustness). Moreover, results of specificity parameter has not been performed.	Analytical method validation study of Drug Product (including linearity, intermediate precision and robustness) is provided	However results of specificity parameter has not been submitted yet.
	Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution medium used by the firm is 0.1NHCl (pH 1.2) with 50 rpm. using USP type II apparatus. Justification to be provided for selection of dissolution medium	Firm has provided the comparative dissolution of the product in all three medias as per ICH guidelines i.e 0.1NHCl , acetate buffer pH 4.5 and phosphate pH 6.8. The dissolution profile of product in 0.1NHCl and acetate buffer pH 4.5 is equal.	
	Justify selection of wavelength (ʎ max) for assay of Drug Product while Drug substance manufacturer adopted analytical wavelength (ʎ max) as 230nm	The raw material was tested using same method as of API manufacturer and detection wavelength of 230nm was used Analytical method for Drug product was developed and validated. While optimization of analytical method for Drug product the UV spectra was observed and maximum absorbance was found to be at 254nm, so this wavelength was used. The method was validated as per ICH guidelines and USP	

	Clarify date of fee submission Prazan 20mg Tablet since "invalid date" has been shown on DRAP fee portal (https://e.dra.gov.pk/)	Firm provided copy of challan no. 989296091316 dated 17/01/2023 wherein Prazan 20mg Tablet was mentioned.	Verified. Paid date has been updated on DRAP fee portal(https://e.dra.gov.pk/)

Decision: Approved.

- **Before issuance of registration letter firm will submit revised dissolution method in line with innovator i.e USFDA approved formulation VOQUEZNA**
- **Before issuance of registration letter firm will submit Analytical method validation study of Drug Product (including specificity parameter).**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1025.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd Plot No 35-A, Punjab Small Industrial Estate, Taxila
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd Plot No 35-A, Punjab Small Industrial Estate, Taxila
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 37338: 21-12-2022
	Details of fee submitted	PKR 30,000/- : invalid date
	The proposed proprietary name / brand name	Vonapp 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 10mg by Searle Pharmaceutical
	Proposed Pack size	As per SRO
Evaluation by PEC (XX):		
3.2.S.5: Perform Analytical method validation study of Drug Substance (including linearity, intermediate precision and robustness) by Drug product manufacturer. Moreover, results of specificity parameter has not been performed. 3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution medium used by the firm is Phosphate buffer (pH 6.8) with 75 rpm. using USP type I apparatus. Justification to be provided for selection of dissolution medium, rpm and type of apparatus.		
Decision: Deferred for submission of above mentioned shortcomings.		
1026.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd Plot No 35-A, Punjab Small Industrial Estate, Taxila

	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd Plot No 35-A, Punjab Small Industrial Estate, Taxila
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 37339: 21-12-2022
	Details of fee submitted	PKR 30,000/- : dated 16.12.2022
	The proposed proprietary name / brand name	Vonapp 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	As per Innovator's specification
	The status in reference regulatory authorities	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 20mg by Searle Pharmaceutical
	Proposed Pack size	As per SRO
Evaluation by PEC (XX):		
3.2.S.5: Perform Analytical method validation study of Drug Substance (including linearity, intermediate precision and robustness) by Drug product manufacturer. Moreover, results of specificity parameter has not been performed. 3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution medium used by the firm is Phosphate buffer (pH 6.8) with 75 rpm. using USP type I apparatus. Justification to be provided for selection of dissolution medium, rpm and type of apparatus.		
Decision: Deferred for submission of above mentioned shortcomings.		

1027.	Name, address of Applicant / Marketing Authorization Holder	M/s Linta Pharmaceuticals, Pvt Ltd. Plot No. 3 Street No S-5, National Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Linta Pharmaceuticals, Pvt Ltd. Plot No. 3 Street No S-5, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 2987: 01-02-2023
	Details of fee submitted	PKR 30,000/- : 10-01-2023
	The proposed proprietary name / brand name	Vonopraz 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	In house specification
	Reference to Finished product specifications	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vonozan Tablet 10mg by Getz Pharmaceutical

	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer.	Firm has provided copy of GMP certificate based on inspection dated 21-12-2023	Complied
	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from both Drug Substance and Drug Product manufacturer	CoA from both Drug substance and Drug product manufacturer (Batch no VPF/30020821M) is provided.	Tests like fumaric acid content (ODB) and residue on ignitions (performed by DS manufacturer) have not been performed by Drug product manufacturer.
	Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution medium used by the firm is 0.1NHCl (pH 1.2) with 50 rpm. using USP type II apparatus. Justification to be provided for selection of dissolution medium.	It is submitted that developmental studies of Vonoprazan tablets 10mg & 20mg before approval of USFDA approved formulation VOQUEZNA dissolution medium. Considering solubility of vonoprazan we have selected 0.1N HCl as dissolution medium. Now as the USFDA has clarified dissolution conditions i.e acetate buffer pH 4.5 with 50 rpm. using USP type II apparatus we are shifting the dissolution specification as per USFDA. **Fee of Rs 7500/- is provided for said variation.**	Challan No 750697829 Dated 21/05/2024 Verified from DRAP fee portal
	Since firm adopted finished product specification as manufacturer's specification hence data to be submitted as per 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023.	It was typographic error. We are applying "as per innovator's specification".	
	Provide documents for the procurement of API with approval from DRAP	Commercial invoice No exp/i/21-22/0297 dated 08/09/2021 confirming import of vonoprazan fumarate 0.183kg (Batch no VPF/30020821M) Cleared by DRAP (I&E) 22/11/2021	Complied

Decision: Approved.

- **Before issuance of registration letter firm will submit fee of Rs 7500/- on account of pre-registration variation as per S.R.O 496(I)12023 dated 17th April, 2023.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1028.	Name, address of Applicant / Marketing Authorization Holder	M/s Linta Pharmaceuticals, Pvt Ltd. Plot No. 3 Street No S-5, National Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Linta Pharmaceuticals, Pvt Ltd. Plot No. 3 Street No S-5, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No & date of submission	Form 5F: Dy. No. 2988: 01-02-2023
	Details of fee submitted	PKR 30,000/- : 10-01-2023
	The proposed proprietary name / brand name	Vonopraz 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan (as Fumarate)…20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	In house specification
	The status in reference regulatory authorities	Takecab Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vonozan Tablet 20mg by Getz Pharmaceutical
	Proposed Pack size	As per SRO

Evaluation by PEC (XX):

Sr.#	Observations	Reply	Remarks
	Provide updated GMP status of finished product manufacturer.	Firm has provided copy of GMP certificate based on inspection dated 21-12-2023	Complied
	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from both Drug Substance and Drug Product manufacturer	CoA from both Drug substance and Drug product manufacturer (Batch no VPF/30020821M) is provided.	Tests like fumaric acid content (ODB) and residue on ignitions (performed by DS manufacturer) have not been performed by Drug product manufacturer.
	Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm using USP type II apparatus while dissolution	It is submitted that developmental studies of Vonoprazan tablets 10mg & 20mg before approval of USFDA approved formulation VOQUEZNA dissolution medium.	Challan No 10456891 Dated 21/05/2024 Verified from DRAP fee portal

	medium used by the firm is 0.1NHCl (pH 1.2) with 50 rpm. using USP type II apparatus. Justification to be provided for selection of dissolution medium.	Considering solubility of vonoprazan we have selected 0.1N HCl as dissolution medium. Now as the USFDA has clarified dissolution conditions i.e acetate buffer pH 4.5 with 50 rpm. using USP type II apparatus we are shifting the dissolution specification as per USFDA. Fee of Rs 7500/- is provided for said variation.	
	Since firm adopted finished product specification as manufacturer's specification hence data to be submitted as per 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023.	It was typographic error. We are applying "as per inniovator's specification".	
	Provide documents for the procurement of API with approval from DRAP	Commercial invoice No exp/i/21-22/0297 dated 08/09/2021 confirming import of vonoprazan fumarate 0.183kg (Batch no VPF/30020821M) Cleared by DRAP (I&E) 22/11/2021	Complied

Decision: Approved.

- **Before issuance of registration letter firm will submit fee of Rs 7500/- on account of pre-registration variation as per S.R.O 496(I)12023 dated 17th April, 2023.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Priority consideration on account of Export Facilitation:

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements
Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-II (EFD) dated 29.05.2024:

1029.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilson's Pharmaceuticals, Plot No 387-388 & 366 I-9/3 , Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No 387-388 & 366 I-9/3 , Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has provided GMP certificate based on inspection dated 28.07.2022 valid for 2 years
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 30-11-2022 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21976 (R&I) DRAP, dated 06/09/2023
	Details of fee submitted	PKR 30,000/- Dated 23-08-2023
	The proposed proprietary name / brand name	Oprazon 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……..……..….10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 10's, 14's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	Voniza Tablet 10mg Hilton pharma Reg No 108573
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd Block No 82/B ECP road AT& POST Karakhadi,-391 450 Dist-Vadora Gujrat state India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(VPF/30021020, VPF/30031020, VPF/30041020)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Voniza 10mg tablet by M/s Hilton Pharmaceutical (Lot No 143489) Quality parameters such as identification, dissolution, Content uniformity, DT and assay etc were compared. CDP has been performed against the same brand that is Voniza 10mg tablet by M/s Hilton Pharmaceutical in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Ami Life Sciences Pvt Ltd Block No 82/B ECP road AT& POST Karakhadi,-391 450 Dist-Vadora Gujrat state India.		
API Lot No.	VPF30100921		
Description of Pack (Container closure system)	Alu-Alu Blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	16-04-2022	16-04-2022	16-04-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 22043267 dated 18/04/2022 issued by Food and Drug Control Administration Gujrat state India valid till 17th April 2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# Exp/I/21-22/0500 dated 30th November 2021, with received quantity i.e. 0.325Kg) for the purchase of Vonoprazan fumarate from Ami Life Sciences Pvt Ltd and clearance certificate from DRAP dated 30/12/2021 (batch no. VPF30100921)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
	3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) while dissolution medium used by the firm is 0.1NHCl. .Justification to be provided for selection of dissolution medium.

Reply:
It is submitted that the M/s Wilson's Pharmaceuticals had conducted the dissolution of Vonoprazan tablets 10mg & 20mg Dated April 2022 with 0.1N HCl as mentioned in registration application, whereas the FDA has approved dissolution medium acetate buffer pH 4.5 dated 01-11-2023 for Voquezna Tablet
It is pertinent to mention here that the product vonoprazan fumarate is not a compendial product and its dissolution method was also not available in any Pharmacopoeia as well as in any reference literature at that time. As per literature review the product was equally soluble in all 3 pH mediums i.e.1.2, 4.5 & 6.8.
Due to high release of vonoprazan in all mediums we have selected 0.1N HCl as dissolution medium.

Decision: Approved.

- **Before issuance of registration letter firm will submit revised dissolution method in line with innovator i.e USFDA approved formulation VOQUEZNA.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

1030.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilson's Pharmaceuticals, Plot No 387-388 & 366 I-9/3 , Industrial Area, Islamabad

	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No 387-388 & 366 I-9/3 , Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate based on inspection dated 28.07.2022 valid for 2 years
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 30-11-2022 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22462 (R&I) DRAP, dated 12/09/2023
	Details of fee submitted	PKR 30,000/- Dated 23-08-2023
	The proposed proprietary name / brand name	Oprazon 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq to Vonoprazan……..……..….20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 10's, 14's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	Voniza Tablet 20mg Hilton pharma Reg No 108572
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd Block No 82/B ECP road AT& POST Karakhadi,-391 450 Dist-Vadora Gujrat state India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(VPF/30021020, VPF/30031020, VPF/30041020)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Voniza 20mg tablet by M/s Hilton Pharmaceutical (Lot No 144815) Quality parameters such as identification, dissolution, Content uniformity, DT and assay etc were compared. CDP has been performed against the same brand that is Voniza 20mg tablet by M/s Hilton Pharmaceutical in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Ami Life Sciences Pvt Ltd Block No 82/B ECP road AT& POST Karakhadi,-391 450 Dist-Vadora Gujrat state India.		
API Lot No.	VPF30100921		
Description of Pack (Container closure system)	Alu-Alu Blister packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1500 tab	1500 tab	1500 tab

Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	30-05-2022	30-05-2022	30-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No 22043267 dated 18/04/2022 issued by Food and Drug Control Administration Gujrat state India valid till 17th April 2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# Exp/I/21-22/0500 dated 30th November 2021, with received quantity i.e. 0.325Kg) for the purchase of Vonoprazan fumarate from Ami Life Sciences Pvt Ltd and clearance certificate from DRAP dated 30/12/2021 (batch no. VPF30100921)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
	3.2.P.5 Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of vonoprazan tablet was 0.05M acetate buffer (pH 4.5) while dissolution medium used by the firm is 0.1NHCl. .Justification to be provided for selection of dissolution medium.

Reply:
It is submitted that the M/s Wilson's Pharmaceuticals had conducted the dissolution of Vonoprazan tablets 10mg & 20mg Dated April 2022 with 0.1N HCl as mentioned in registration application, whereas the FDA has approved dissolution medium acetate buffer pH 4.5 dated 01-11-2023 for Voquezna Tablet
It is pertinent to mention here that the product vonoprazan fumarate is not a compendial product and its dissolution method was also not available in any Pharmacopoeia as well as in any reference literature at that time. As per literature review the product was equally soluble in all 3 pH mediums i.e.1.2, 4.5 & 6.8.
Due to high release of vonoprazan in all mediums we have selected 0.1N HCl as dissolution medium.

Decision: Approved.

- **Before issuance of registration letter firm will submit revised dissolution method in line with innovator i.e USFDA approved formulation VOQUEZNA.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Evaluator PEC-XXI

Agenda Item No. 01:

Priority Applications of Human Drugs (Locally Manufactured) applied on Form - 5F on the basis of Export Facilitation.

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-II (EFD) dated 13th September 2023 from Deputy Director (PR-II/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s Martin Dow Marker Limited, Quetta) have achieved the benchmark of export of more than 100,000 USD during the fiscal year 2022 - 2023 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

1031.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited 7, Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited 7, Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Firm has submitted copy of Renewal of DML Letter vide No. F. 4-2/86-Lic(Vol-VII)(Pt) dated 17th June 2021, mentioning Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9495 dated 10 APR 2023
	Details of fee submitted	PKR 75,000/- Dated 01-03-2023 (Challan / Receipt # 0827478891)
	The proposed proprietary name / brand name	**VERICIGUAT 2.5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet contains: Vericiguat … 2.5mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	C01DX22, Other vasodilators used in cardiac diseases.
	Pharmaceutical form of applied drug	White to off white color, round, biconvex shaped film coated Tablets.
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VERQUVO 2.5mg Tablets, USFDA Approved.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for **06 Months**.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VERQUVO 2.5mg Tablets by performing quality tests (Assay and Dissolution). Firm has submitted CDP results of their product against VERQUVO 2.5mg Tablets in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., China.		
API Lot No.	PIVCG-2110001		
Description of Pack (Container closure system)	ALU/ALU blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial - 01	Trial – 02	Trial - 03
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product GLUCOVANCE Tablets 1000mg/5mg discussed in 293rd Meeting of Registration Board (6th – 8th January, 2020).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP Certificate is not from the concerned Regulatory Authority of Country of Origin and is not verifiable.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021 has been submitted. **However, enclosed clearance was issued with remarks "Restricted Consumption".**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	Copy of GMP Certificate issued by Nantong Chemical & Medical Industry Assoication, China. **However, the same cannot be verified since it's not from concerned Regulatory Authority of Country of Origin.**
ii.	Please provide valid GMP status of the firm (FPP Manufacturer).	Copy of GMP Certificate has been submitted based on Inspection conducted on 15th and 16th of January 2024.
iii.	2.3.S.4.4 a) Please provide COA of API Manufacturer for Batch SYVCG-210601.	Submitted
iv.	2.3.S.7.1 a) Please provide information regarding proposed Shelf Life of API / Drug Substance as the completed testing intervals for Long-Term Stability Study is 06 Months.	Firm has submitted **12 Months** (Long Term) Stability Study Data Sheets from API Manufacturer. Moreover, the proposed Shelf Life as per submitted COA of API is also 12 Months.
v.	In Sections 2.3.P.2.1.1 and 3.2.P.2.1.1, it has been mentioned that *'API-Excipient compatibility is not required to be established as evidence is provided (**Takecab 10mg Film Coated Tablet**) that the excipients are present in the comparator product*'. Please clarify.	Firm has submitted that the excipients used are as per Innovator's formulation (Verquvo Tablet) and the product is found physically and chemically stable during stability studies.
vi.	2.3.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	Submitted
vii.	2.3.P.5.6 Justification of Specifications, it has been mentioned that ***'Specifications are based on MDM Specifications***', however reference to Finished Pharmaceutical Specifications have been claimed **'As per Innovator's Specs**" in Application Form. Please justify.	Firm has submitted that the specifications are based on **Innovator's specifications.**
viii.	Please provide approval for utilization / consumption of the enclosed Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021, since the same was issued with remarks "Restricted Consumption".	Firm has submitted copy of said invoice with remarks from AD (I&E), DRAP Quetta as '*Physically verified in the premises, permitted to consume'.*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.**		
1032.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited 7, Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited 7, Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Firm has submitted copy of Renewal of DML Letter vide No. F. 4-2/86-Lic(Vol-VII)(Pt) dated 17th June 2021, mentioning Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9496 dated 10 APR 2023
	Details of fee submitted	PKR 75,000/- Dated 01-03-2023 (Challan / Receipt # 98581925)
	The proposed proprietary name / brand name	**VERICIGUAT 5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet contains: Vericiguat … 5mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	C01DX22, Other vasodilators used in cardiac diseases.
	Pharmaceutical form of applied drug	Brown color, round, biconvex shaped film coated Tablets.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VERQUVO 5mg Tablets, USFDA Approved.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No.2 Tonghai Si Road, Yangkou Chemical Industrial Park,

		Rudong Coastal Economic Development Zone, Nantong, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for **06 Months**.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VERQUVO 5mg Tablets by performing quality tests (Assay and Dissolution). Firm has submitted CDP results of their product against VERQUVO 5mg Tablets in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
API Lot No.	PIVCG-2110001
Description of Pack (Container closure system)	ALU/ALU blister
Stability Storage	Real time: 30°C ± 2°C / 65% ± 5%RH

Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial - 01	Trial – 02	Trial - 03
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product GLUCOVANCE Tablets 1000mg/5mg discussed in 293rd Meeting of Registration Board (6th – 8th January, 2020).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP Certificate is not from the concerned Regulatory Authority of Country of Origin and is not verifiable.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021 has been submitted. **However, enclosed clearance was issued with remarks "Restricted Consumption".**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	Copy of GMP Certificate issued by Nantong Chemical & Medical Industry Assoication, China. **However, the same cannot be verified since it's not from concerned Regulatory Authority of Country of Origin.**

ii.	Please provide valid GMP status of the firm (FPP Manufacturer).	Copy of GMP Certificate has been submitted based on Inspection conducted on 15th and 16th of January 2024.
iii.	2.3.S.4.4 a) Please provide COA of API Manufacturer for Batch SYVCG-210601.	Submitted
iv.	2.3.S.7.1 a) Please provide information regarding proposed Shelf Life of API / Drug Substance as the completed testing intervals for Long-Term Stability Study is 06 Months.	Firm has submitted **12 Months** (Long Term) Stability Study Data Sheets from API Manufacturer. Moreover, the proposed Shelf Life as per submitted COA of API is also 12 Months.
v.	2.3.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	Submitted
vi.	2.3.P.5.6 Justification of Specifications, it has been mentioned that ***'Specifications are based on MDM Specifications***', however reference to Finished Pharmaceutical Specifications have been claimed **'As per Innovator's Specs**" in Application Form. Please justify.	Firm has submitted that the specifications are based on **Innovator's specifications.**
vii.	Significant change (5% change in Assay from its initial value) has been observed in Accelerated Stability Testing of Vericiguat Tablets 5mg, **Batch No. T-01**. Please justify.	Firm have submitted that the **highlighted significant change may be due to analyst handling variation** and considering the satisfactory Long-term stability data till complete shelf life (24 Months), it can be neglected.
viii.	Significant change (5% change in Assay from its initial value) has been observed in Accelerated Stability Testing of Vericiguat Tablets 5mg, **Batch No. T-03**. Please justify.	Firm have submitted that the **highlighted significant change may be due to analyst handling variation** and considering the satisfactory Long-term stability data till complete shelf life (24 Months), it can be neglected.
ix.	Please provide approval for utilization / consumption of the enclosed Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021, since the same was issued with remarks "Restricted Consumption".	Firm has submitted copy of said invoice with remarks from AD (I&E), DRAP Quetta as '*Physically verified in the premises, permitted to consume'.*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.		
1033.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited 7, Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited 7, Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Firm has submitted copy of Renewal of DML Letter vide No. F. 4-2/86-Lic(Vol-VII)(Pt) dated 17th June 2021, mentioning Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9497 dated 10 APR 2023
	Details of fee submitted	PKR 75,000/- Dated 01-03-2023 (Challan / Receipt # 44814187)
	The proposed proprietary name / brand name	**VERICIGUAT 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet contains: Vericiguat … 10mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	C01DX22, Other vasodilators used in cardiac diseases.
	Pharmaceutical form of applied drug	Yellow color, round, biconvex shaped film coated Tablets.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VERQUVO 10mg Tablets, USFDA Approved.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for **06 Months**.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VERQUVO 10mg Tablets by performing quality tests (Assay and Dissolution). Firm has submitted CDP results of their product against VERQUVO 10mg Tablets in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
API Lot No.	PIVCG-2110001
Description of Pack (Container closure system)	ALU/ALU blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 Months Accelerated: 6 Months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial - 01	Trial – 02	Trial - 03
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product GLUCOVANCE Tablets 1000mg/5mg discussed in 293rd Meeting of Registration Board (6th – 8th January, 2020).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP Certificate is not from the concerned Regulatory Authority of Country of Origin and is not verifiable.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021 has been submitted. **However, enclosed clearance was issued with remarks "Restricted Consumption".**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	Copy of GMP Certificate issued by Nantong Chemical & Medical Industry Assoication, China. **However, the same cannot be verified since it's not from concerned Regulatory Authority of Country of Origin.**

ii.	Please provide valid GMP status of the firm (FPP Manufacturer).	Copy of GMP Certificate has been submitted based on Inspection conducted on 15th and 16th of January 2024.
iii.	2.3.S.4.4 a) Please provide COA of API Manufacturer for Batch SYVCG-210601.	Submitted
iv.	2.3.S.7.1 a) Please provide information regarding proposed Shelf Life of API / Drug Substance as the completed testing intervals for Long-Term Stability Study is 06 Months.	Firm has submitted **12 Months** (Long Term) Stability Study Data Sheets from API Manufacturer. Moreover, the proposed Shelf Life as per submitted COA of API is also 12 Months.
v.	2.3.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	Submitted
vi.	2.3.P.5.6 Justification of Specifications, it has been mentioned that ***'Specifications are based on MDM Specifications***', however reference to Finished Pharmaceutical Specifications have been claimed **'As per Innovator's Specs**" in Application Form. Please justify.	Firm has submitted that the specifications are based on **Innovator's specifications.**
vii.	Please provide approval for utilization / consumption of the enclosed Commercial Invoice No. CYI21312 dated OCT 15, 2021 for import of 1.5Kgs VERICIGUAT, Batch No. PIVCG-2110001, cleared by AD(I&E) DRAP Quetta vide No. 958/DRAP(Q) dated 12-11-2021, since the same was issued with remarks "Restricted Consumption".	Firm has submitted copy of said invoice with remarks from AD (I&E), DRAP Quetta as '*Physically verified in the premises, permitted to consume'.*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.

Agenda Item No. 02: Deferred Cases of Previous Meetings

1034.	**Name, address of Applicant / Marketing Authorization Holder**	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract

		giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2007 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17611 dated 16 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 6773937439)
	The proposed proprietary name / brand name	**VORTIX 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vortioxetine HBr eq. to Vortioxetione … 5mg (Innovator's Specification)
	Pharmacotherapeutic Group of (API)	N06AX26, Other antidepressants.
	Pharmaceutical form of applied drug	Round shaped biconvex film coated tablets
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRINTELLIX Tablet 5mg of TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	VRONTIL 5mg Tablet of M/s Genix Pharma, Karachi.
	Name and address of API manufacturer.	Lianyungang Jari Pharmaceutical Co. Ltd. Room 1216, Shimao Plaza, Xinbei district, Changzhou, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months. Batches 20140401, 20140402 and 20140403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VORNEU Tablet 5mg manufactured by Hilton Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product VORNEU Tablet 5mg manufactured by Hilton Pharma (Pvt) Ltd., in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product respectively.

STABILITY STUDY DATA			
Manufacturer of API	Lianyungang Jari Pharmaceutical Co. Ltd., China.		
API Lot No.	20210403		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VRT 21-073	VRT 21-074	VRT 21-075
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	20-07-2021	20-07-2021	20-07-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Firm has referred to their Product Specific Inspection conducted for Empaglif 10mg Tablet (Empagliflozin) & Empaglif 25mg Tablet (Empagliflozin) presented in 296th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP is not issued by concerned regulatory authority of country of origin
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance for Commercial Invoice No. 21YX0033L dated 29.04.2021, cleared by AD (I&E) DRAP, Islamabad on 21-06-2021, specifying 0.3Kg of Vortioxetine Hydrobromide.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviours. TRINTELLIX is not approved for use in pediatric patients.

The following observations / shortcomings were communicated to the applicant and their response was received as follows:

Observations / Shortcomings	Response of the applicant
• Please provide evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	**The firm has submitted that the same has bee requested from API Manufacturer and will b shared after received from API Manufacturer**
• Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	The firm has submitted evidence for VORNE 5mg Tablet B. No. 138718.
• 2.3.P.3.3 The enclosed Manufacturing Process Flow Chart is a general flow for tablet section. Please provide the same specific for manufacturing of applied drug product.	Submitted.
• 3.2.P.8 A 'Significant change' (5% change in assay from its initial value) has occurred between initial and 3 months' testing at the accelerated as well as real time storage conditions of Batch No. VRT 21-075. Please justify.	**The firm has submitted revised stability da summary sheet stating that there was 'Typographic error' in submitted stabili summary sheet, in which result of dissolutio were written in assay.**
• Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	**Not submitted**

• Please provide GMP of applicant (FPP Manufacturer).	Firm has submitted copy of GMP Certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021 valid till 02-08-2023. Furthermore, the firm has stated that they have applied for renewal of GMP Certificate as well.
• Please provide summary of consumption of material (API) imported v/s consumed for manufacturing of Stability Batches / QC testing of each applied strength.	Submitted

Decision of 331st Meeting:
Registration Board deferred the case for submission of reply to the following shortcomings: -

- **Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).**
- **Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Remarks of Evaluator: The firm have submitted as follows: -

Shortcomings	Firm's Submission
• Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	Firm has submitted **revised Section 3.2.S.4** (Method of Analysis) specifying Tests for Identification of Crystal Form and Microbial Limits.
• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	Firm has submitted GMP Audit Report, Ref. No. Nil, issued by Lianyungang Drug Administration. **However, the same cannot be verified online.**
• Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted Fee of PKR 7,500/- vide Challan No. 27737355316 for VORTIX 5mg Tablets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.

1035.	**Name, address of Applicant / Marketing Authorization Holder**	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2007 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13315 dated 01 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 7427387375)
	The proposed proprietary name / brand name	**VORTIX 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vortioxetine HBr eq. to Vortioxetione … 10mg (Innovator's Specification)
	Pharmacotherapeutic Group of (API)	N06AX26, Other antidepressants.
	Pharmaceutical form of applied drug	Round shaped biconvex film coated tablets
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRINTELLIX Tablet 10mg of TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	VRONTIL 10mg Tablet of M/s Genix Pharma, Karachi.
	Name and address of API manufacturer.	Lianyungang Jari Pharmaceutical Co. Ltd. Room 1216, Shimao Plaza, Xinbei district, Changzhou, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months. Batches 20140401, 20140402 and 20140403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VORNEU Tablet 10mg manufactured by Hilton Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product VORNEU Tablet 10mg manufactured by Hilton Pharma (Pvt) Ltd., in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product respectively.

STABILITY STUDY DATA			
Manufacturer of API	Lianyungang Jari Pharmaceutical Co. Ltd., China.		
API Lot No.	20210403		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VRT 21-076	VRT 21-077	VRT 21-078
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	31-07-2021	31-07-2021	31-07-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Firm has referred to their Product Specific Inspection conducted for Empaglif 10mg Tablet (Empagliflozin) & Empaglif 25mg Tablet (Empagliflozin) presented in 296th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP is not issued by concerned regulatory authority of country of origin
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance for Commercial Invoice No. 21YX0033L dated 29.04.2021, cleared by AD (I&E) DRAP, Islamabad on 21-06-2021, specifying 0.3Kg of Vortioxetine Hydrobromide.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviours. TRINTELLIX is not approved for use in pediatric patients.

The following observations / shortcomings were communicated to the applicant and their response was received as follows:

Observations / Shortcomings	Response of the applicant
• Please provide evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	**The firm has submitted that the same has bee requested from API Manufacturer and will b shared after received from API Manufacturer**
• Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	The firm has submitted evidence for VORNE 10mg Tablet B. No. 138685.
• 2.3.P.3.3 The enclosed Manufacturing Process Flow Chart is a general flow for tablet section. Please provide the same specific for manufacturing of applied drug product.	Submitted.
• Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	**Not submitted**
• Please provide GMP of applicant (FPP Manufacturer).	Firm has submitted copy of GMP Certifica dated 28-02-2022 issued based on inspectio conducted on 03-08-2021 valid till 02-08-202 Furthermore, the firm has stated that they hav applied for renewal of GMP Certificate as wel

• Please provide summary of consumption of material (API) imported v/s consumed for manufacturing of Stability Batches / QC testing of each applied strength.	Submitted

Decision of 331st Meeting:
Registration Board deferred the case for submission of reply to the following shortcomings: -

- **Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).**
- **Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Remarks of Evaluator: The firm have submitted as follows: -

Shortcomings	Firm's Submission
• Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	Firm has submitted **revised Section 3.2.S.4** (Method of Analysis) specifying Tests for Identification of Crystal Form and Microbial Limits.
• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	Firm has submitted GMP Audit Report, Ref. No. Nil, issued by Lianyungang Drug Administration. **However, the same cannot be verified online.**
• Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted Fee of PKR 7,500/- vide Challan Nos 8344071732 for VORTIX 10mg Tablets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.

1036.	**Name, address of Applicant / Marketing Authorization Holder**	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2007 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13316 dated 01 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 25590526791)
	The proposed proprietary name / brand name	**VORTIX 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vortioxetine HBr eq. to Vortioxetione … 15mg (Innovator's Specification)
	Pharmacotherapeutic Group of (API)	N06AX26, Other antidepressants.
	Pharmaceutical form of applied drug	Round shaped biconvex film coated tablets
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRINTELLIX Tablet 15mg of TAKEDA PHARMS USA (USFDA Discontinued). **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	VRONTIL 15mg Tablet of M/s Genix Pharma, Karachi.
	Name and address of API manufacturer.	Lianyungang Jari Pharmaceutical Co. Ltd. Room 1216, Shimao Plaza, Xinbei district, Changzhou, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months. Batches 20140401, 20140402 and 20140403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VORNEU Tablet 15mg manufactured by Hilton Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product VORNEU Tablet 15mg manufactured by Hilton Pharma (Pvt) Ltd., in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product respectively.

STABILITY STUDY DATA			
Manufacturer of API	Lianyungang Jari Pharmaceutical Co. Ltd., China.		
API Lot No.	20210403		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VRT 21-087	VRT 21-088	VRT 21-089
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	02-08-2021	02-08-2021	02-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Firm has referred to their Product Specific Inspection conducted for Empaglif 10mg Tablet (Empagliflozin) & Empaglif

		25mg Tablet (Empagliflozin) presented in 296th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP is not issued by concerned regulatory authority of country of origin
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance for Commercial Invoice No. 21YX0033L dated 29.04.2021, cleared by AD (I&E) DRAP, Islamabad on 21-06-2021, specifying 0.3Kg of Vortioxetine Hydrobromide.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviours. TRINTELLIX is not approved for use in pediatric patients.

The following observations / shortcomings were communicated to the applicant and their response was received as follows:

Observations / Shortcomings	Response of the applicant
• Please provide evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	**The firm has submitted that the same has bee requested from API Manufacturer and will b shared after received from API Manufacturer**
• Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	The firm has submitted evidence for VORNE 15mg Tablet B. No. 139239.
• 2.3.P.3.3 The enclosed Manufacturing Process Flow Chart is a general flow for tablet section. Please provide the same specific for manufacturing of applied drug product.	Submitted.
• Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	**Not submitted**
• Please provide GMP of applicant (FPP Manufacturer).	Firm has submitted copy of GMP Certifica dated 28-02-2022 issued based on inspectio conducted on 03-08-2021 valid till 02-08-202 Furthermore, the firm has stated that they hav applied for renewal of GMP Certificate as wel
• Please provide summary of consumption of material (API) imported v/s consumed for manufacturing of Stability Batches / QC testing of each applied strength.	Submitted

Decision of 331st Meeting:

Registration Board deferred the case for submission of reply to the following shortcomings: -

- **Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).**
- **Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Remarks of Evaluator: The firm have submitted as follows: -

Shortcomings	Firm's Submission
• Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	Firm has submitted **revised Section 3.2.S.4** (Method of Analysis) specifying Tests for Identification of Crystal Form and Microbial Limits.
• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	Firm has submitted GMP Audit Report, Ref. No. Nil, issued by Lianyungang Drug Administration. **However, the same cannot be verified online.**
• Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted Fee of PKR 7,500/- vide Challan No. 4260757861 for VORTIX 15mg Tablets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.

1037.	**Name, address of Applicant / Marketing Authorization Holder**	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	Bio-Labs(Pvt.) Ltd., Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2007 specifying Tablet (General) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17612 dated 16 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 50756815)
	The proposed proprietary name / brand name	**VORTIX 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vortioxetine HBr eq. to Vortioxetione … 20mg (Innovator's Specification)
	Pharmacotherapeutic Group of (API)	N06AX26, Other antidepressants.
	Pharmaceutical form of applied drug	Round shaped biconvex film coated tablets
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRINTELLIX Tablet 20mg of TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	VRONTIL 20mg Tablet of M/s Genix Pharma, Karachi
	Name and address of API manufacturer.	Lianyungang Jari Pharmaceutical Co. Ltd. Room 1216, Shimao Plaza, Xinbei district, Changzhou, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for

		24 Months. Batches 20140401, 20140402 and 20140403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against VORNEU Tablet 20mg manufactured by Hilton Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product VORNEU Tablet 20mg manufactured by Hilton Pharma (Pvt) Ltd., in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product respectively.

STABILITY STUDY DATA			
Manufacturer of API	Lianyungang Jari Pharmaceutical Co. Ltd., China.		
API Lot No.	20210403		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VRT 21-092	VRT 21-093	VRT 21-094
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Firm has referred to their Product Specific Inspection conducted for Empaglif 10mg Tablet (Empagliflozin) & Empaglif 25mg Tablet (Empagliflozin) presented in 296th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Enclosed GMP is not issued by concerned regulatory authority of country of origin

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance for Commercial Invoice No. 21YX0033L dated 29.04.2021, cleared by AD (I&E) DRAP, Islamabad on 21-06-2021, specifying 0.3Kg of Vortioxetine Hydrobromide.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviours. TRINTELLIX is not approved for use in pediatric patients.

The following observations / shortcomings were communicated to the applicant and their response was received as follows:

Observations / Shortcomings	Response of the applicant
• Please provide evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	**The firm has submitted that the same has bee requested from API Manufacturer and will b shared after received from API Manufacturer**
• Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	The firm has submitted evidence for VORNE 20mg Tablet B. No. 138698.
• 2.3.P.3.3 The enclosed Manufacturing Process Flow Chart is a general flow for tablet section. Please provide the same specific for manufacturing of applied drug product.	Submitted.
• Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	**Not submitted**
• Please provide GMP of applicant (FPP Manufacturer).	Firm has submitted copy of GMP Certifica dated 28-02-2022 issued based on inspectio conducted on 03-08-2021 valid till 02-08-202 Furthermore, the firm has stated that they hav applied for renewal of GMP Certificate as wel
• Please provide summary of consumption of material (API) imported v/s consumed for manufacturing of Stability Batches / QC testing of each applied strength.	Submitted

Decision of 331st Meeting:

Registration Board deferred the case for submission of reply to the following shortcomings: -

- **Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.**

- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).**
- **Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Remarks of Evaluator: The firm have submitted as follows: -

Shortcomings	Firm's Submission
• Evidence of test for 'identification of Polymorphic form' and 'Microbial Contamination' of API by drug substance manufacturer, since the same has not been included in 3.2.S.4.1 Specifications of API Manufacturer.	Firm has submitted **revised Section 3.2.S.4** (Method of Analysis) specifying Tests for Identification of Crystal Form and Microbial Limits.
• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin (i.e. CFDA).	Firm has submitted GMP Audit Report, Ref. No. Nil, issued by Lianyungang Drug Administration. **However, the same cannot be verified online.**
• Submission of prescribed fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted Fee of PKR 7,500/- vide Challan No. 558602658 for VORTIX 20mg Tablets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit GMP of API manufacturer issued by concerned Regulatory Authority of Country of Origin before issuance of registration letter.

1038.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited Lahore
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited Plot 37-A, Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4930 dated 21-02-2023
	Details of fee submitted	Slip No. 890870611016 PKR 20,000/- dated 31-01-2023 Slip No. 02554272360

		PKR 10,000/- dated 04-11-2021
	The proposed proprietary name / brand name	Levomark 250 mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Levofloxacin hemihydrate equivalent to Levofloxacin USP 250mg (USP Specifications)
	Pharmaceutical form of applied drug	Light yellow oblong film coated tablet
	Pharmacotherapeutic Group of (API)	J01MA12 Anti-infective for Systemic Use, Fluoroquinolones
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin 250 mg Film-coated Tablets by Accord Healthcare Limited UK (MHRA Approved).
	For generic drugs (me-too status)	Leflox 250mg Tablet (Reg. No. 026164) by Getz Pharma.
	GMP status of the Finished product manufacturer	New license granted on 26 – 09 – 2019.
	Name and address of API manufacturer.	Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd. 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches:(LFA-V-20120801ES, LFA-V-20120802ES, LFA-V-20120803ES).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Leflox 250mg Tablet by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Leflox 250mg Tablet by Getz Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product	Method verification studies have submitted including precision, accuracy and specificity.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd. 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR China		
API Lot No.	KY-LFA-M20190968E		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	24-04-2020	24-04-2020	24-04-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190145 issued by China Food & Drugs Administration is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. 2020APE4256 dated 13 April 2020 is submitted. However approval from DRAP is not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm: -

i. Latest GMP Inspection Report (not older than 03 years) is required.

ii. In Analytical Procedure for Levomark 250mg Film Coated Tablet (Document # SAP-106), under test for Dissolution, Medium has been mentioned as 0.1N HCl as well as 0.01N HCl. Clarification is required.

iii. In Stability Study Protocol for Levomark 250mg Film Coated Tablet (Document # SSP-024), the Objective has been stated as "to carry out stability of Levomark 250mg film coated Tablet (Loratadine)". Clarification is required.

iv. Evidence of approval from DRAP (concerned Assistant Director I&E) for procurement of Levofloxacin hemihydrate, API Lot No. KY-LFA-M20190968E is required.

v. Trial Batches were manufactured and placed on Stability in April 2020, however the application for Registration has been filed in February 2023 (with 06 Months Stability Data). Reason for delayed submission is sought.

Decision of 327th Meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator: The firm has submitted as follows:

Shortcomings	Firm's Submission
Latest GMP Inspection Report (not older than 03 years) is required.	Copy of GMP Certificate No. 38/2023-DRAP(AD-27101426183-965) dated 06-04-2023 valid for 03 years from the date of inspection (28-03-2023) has been submitted.
In Analytical Procedure for Levomark 250mg Film Coated Tablet (Document # SAP-106), under test for Dissolution, Medium has been mentioned as 0.1N HCl as well as 0.01N HCl. Clarification is required.	**Typographic Mistake. Firm has submitted revised Analytical Procedure for dissolution mentioning 0.1N HCl Medium.**
In Stability Study Protocol for Levomark 250mg Film Coated Tablet (Document # SSP-024), the Objective has	**Typographic Mistake. Firm has submitted revised Objective of Stability Study Protocol.**

been stated as "to carry out stability of Levomark 250mg film coated Tablet (Loratadine)". Clarification is required.	
Evidence of approval from DRAP (concerned Assistant Director I&E) for procurement of Levofloxacin hemihydrate, API Lot No. KY-LFA-M20190968E is required.	Firm has submitted copy of Letter from AD(I&E) Lahore (Ref. No. 17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019) for Permission to Import APIs, mentioning 3.805 Kgs Levofloxacin Hemihydrate.
Trial Batches were manufactured and placed on Stability in April 2020, however the application for Registration has been filed in February 2023 (with 06 Months Stability Data). Reason for delayed submission is sought	Firm has submitted that ***"dossier of Levomark 250mg film coated tablet was initially submitted to DRAP in January 2021 but unfortunately the file was misplaced and receiving was also lost from our regulatory staff".*** **However, no supporting evidence regarding above claim has been submitted.**

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The firm shall submit full Fee for pre-registration corrections / Typographical Mistakes before issuance of registration letter.

1039.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26-27, 63-67, Sector-27 Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26-27, 63-67, Sector-27 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22140 dated 04-08-2022.
	Details of fee submitted	Slip No. 7682522698 PKR 30,000/- dated 03-06-2022.
	The proposed proprietary name / brand name	Parabac 500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains:

		Sterile Cefoperazone Sodium & Sulbactum Sodium (1:1) … 500mg (Innovator's Specification)
	Pharmaceutical form of applied drug	A white to off-white sterile crystalline powder for Injection, filled and sealed in 8ml clear glass vial with blue colored plastic flip off seal.
	Pharmacotherapeutic Group of (API)	J01DD62, Anti-infectives for Systemic Use, Third-generation Cephalosporins.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone for Intravenous Injection 0.5g (PMDA Japan Approved).
	For generic drugs (me-too status)	2Sum 500mg Injection (Reg. No. 079941) by M/s Healthtek (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	GMP Certificate No. 53/2021-DRAP(K) issued dated 24-12-2021.
	Name and address of API manufacturer.	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: 319109008, 319109009 and 319109010.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer,

		description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against "2Sum 500mg Injection by M/s Healthtek (Pvt.) Ltd, Reg. No. 079941" by performing quality tests (description, pH, Assay, Microbial Limit).
	Analytical method validation / verification of product	Method validation studies have submitted including linearity, specificity, precision, accuracy, range, robustness and system suitability.

STABILITY STUDY DATA			
Manufacturer of API	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, China.		
API Lot No.	3192103009		
Description of Pack (Container closure system)	8ml clear glass sealed vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-1/PB 500mg Inj	TR-2/PB 500mg Inj	TR-3/PB 500mg Inj
Batch Size	2,000 Vials	2,000 Vials	2,000 Vials
Manufacturing Date	10 – 2021	10 – 2021	10 – 2021
Date of Initiation	26-10-2021	26-10-2021	26-10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has referred to their Inspection of Canazin 100mg & 300mg Tablets (Canagliflozin) conducted on 14th March, 2019 and discussed and approved in 289th meeting of Registration Board held on 14th – 16th May, 2019.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. GD20180909 issued by China Food and Drug Administration valid till 05/12/2023 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. CESU210802JZ dated 02-08-2021 cleared on 11/08/2021 by AD (I&E) DRAP Karachi for 200Kgs of Cefoperazone

		Sodium and Sulbactum Sodium (1:1) has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	In 1.5.10 Dosage form of applied drug, b) Description of Dosage Form, it is mentioned as "A white to yellowish orange, sterile crystalline powder, filled and sealed in 20ml clear glass vial with Red color plastic flip off seal". However, the same has been mentioned as "A white to off-white sterile crystalline powder, filled and sealed in 8ml clear glass vial with blue color plastic flip off seal in rest of the dossier". Please clarify	The firm have submitted revised section 1.5.10 Dosage form of applied drug, b) Description of Dosage Form as "A white to off-white sterile crystalline powder, filled and sealed in 8ml clear glass vial with blue color plastic flip off seal in rest of the dossier".
ii.	In 2.3.S.4 Control of the Drug Substance, 2.3.S.4.1 (a) Drug Substance specifications of the Drug Product Manufacturer, the standard specification and reference number has been mentioned as "USP 43" whereas the Tests are conducted as per "In-House" Specifications. Please clarify	The firm have submitted revised section 2.3.S.4 Control of the Drug Substance, 2.3.S.4.1 (a) Drug Substance specifications of the Drug Product Manufacturer as "In-House".
iii.	In 2.3.S.4.5 Justification of Specifications, it is stated that "Cefoperazone sodium and Sulbactum sodium being In-House product is analysed as per Manufacturers Specifications", however the official monograph of Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopoeia. Please justify the reason for not adopting the same	The firm have submitted that the product mentioned in Japanese Pharmacopeia Monograph is freeze lyophilized solution while they are manufacturing product by direct filling of powder aseptically into final container hence both are considered as different products and have different product specifications.
iv.	In 2.3.P.5.4 Batch Analysis, a) Description of the Batches, date of Manufacturing of Batch "TR-3/PB 500mg Inj" is mentioned as "12 – 2019". Please clarify	The firm have submitted revised section 2.3.P.5.4 Batch Analysis, a) Description of the Batches, date of Manufacturing of Batch "TR-3/PB 500mg Inj" as "10 – 2021".
v.	Pharmaceutical Equivalence have been established against "2Sum 500mg Injection by M/s Healthtek (Pvt.) Ltd". Please justify the reason for not establishing the same against Reference / Innovator / Originator Product	The firm have submitted that the innovator Product Magnex 500mg Injection (Cefoperazone + Sulbactum) by Pfizer (Japan) was not available in Pakistan hence they have established Pharmaceutical Equivalence against

		"2Sum 500mg Injection by M/s Healthtek (Pvt.) Ltd".

Decision of 329th Meeting:
Registration Board Referred to Expert Working Group for the review of specifications Cefoperazone Sodium & Sulbactam Sodium for Injection (JP Specifications).
- **Registration Board further decided that firm shall submit full fee of registration for revision of the data submitted in registration application before issuance of Registration letter.**

Remarks of Evaluator: The firm has submitted as follows:-

Shortcomings	Firm's Submission
Registration Board Referred to Expert Working Group for the review of specifications Cefoperazone Sodium & Sulbactam Sodium for Injection (JP Specifications).	Firm has requested to approve their product PARABAC 500mg Injection as per **Innovator's Specifications** while referring to "**Case No. 5 Cefoperazone Sodium & Sulbactam Sodium for Injection (JP Specifications)" of 329th Meeting of Registration Board**, wherein it was decided as under: - **"Decision: Registration Board while considering the above presented information noted the fact that JP monograph of "Cefoperazoene + Sulbactam dry powder for injection" is particular for the drug product manufactured by way of "Freeze-dried (Lyophilized) from solutions in final container while the products being manufactured by using "ready to fill" powder may have different quality profile hence after thorough deliberation, Board decided as under:** **i. Registration applications of "Cefoperazoene + Sulbactam dry powder for injection" may be approved either with Innovator's specifications or Japanese Pharmacopoeia specifications, as per the submission of the applicant.** **ii. Registration applications in instant meeting may also be decided accordingly."**
Registration Board further decided that firm shall submit full fee of registration for revision of the data submitted in registration application before issuance of Registration letter.	**Firm has submitted PKR 30,000/- vide Challan No. 4320879352 as Fee for revised data submission.**

Decision: Approved as per Innovator's Specification.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1040.	**Name, address of Applicant / Importer**	**M/s REVIVE HEALTH CARE** **Address:** 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore.
	Details of Drug Sale License of importer	**License No:** 05-352-0065-031159D **Address:** 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore. **Address of Godown:** N/A **Validity:** 21.05.2027 **Status:** VALID **Renewal:** 09 May, 2022.
	Name and address of marketing authorization holder (abroad)	**M/s SPAL Private Limited,** Plot No. 12, Biotech Park, Phase-II, Lalgadi Malakpet Shameerpet, Medchal-Malkajgiri Dist, Hyderabad, Telangan State – 500101, India.
	Name, address of manufacturer(s)	**M/s SPAL Private Limited,** Plot No. 12, Biotech Park, Phase-II, Lalgadi Malakpet Shameerpet, Medchal-Malkajgiri Dist, Hyderabad, Telangan State – 500101, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **Scanned Copy** of legalized & notarized CoPP Certificate No. 4429584/TS/2023 dated 08-08-2023 issued by Drugs Control Administration, Telangana State for Carboplatin Concentrate for Solution for Infusion BP 450mg/45ml (CARBO SPAL-L 450), valid up to 05/10/2025. The CoPP mentions free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once in a year.
	Details of letter of authorization / sole agency agreement	Firm has submitted **Photocopy** of notarized 'Authorization Letter' issued by **M/s SP Accure Labs Private Limited**. The letter certifies that M/s SP Accure Labs Private Limited authorizes Revive Healthcare as their "EXCLUSIVE DISTRIBUTOR" for their products mentioned in **Annex 1**, for Pakistan. The authorization letter is signed dated

		07/06/2022 and is valid till further Notice.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26291 dated 31 OCT 2023
	Details of fee submitted	PKR 150,000/- dated 26/10/2023 (Challan / Receipt # 0299928286)
	The proposed proprietary name / brand name	**CARBO SPAL-L 450 Concentrate for Solution for Infusion, 450mg/45ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboplatin (Ph.Eur.) … 10mg (BP Specifications)
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion
	Pharmacotherapeutic Group of (API)	L01XA02 Antineoplastic and Immunomodulating Agents, Platinum compounds.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	45ml Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	KEMOCARB 450mg INJECTION by M/s ATCO Laboratories Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	SUN Pharmaceutical Industries Limited, India.

		A-7/A-8, M.I.D.C, Industrial Area Ahmedabad Nagar 414111 Maharashtra State, India.
	Module-III Drug Substance:	Firm has submitted drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at Accelerated (40 ± 2°C / 75% RH ± 5%) for 6 Months and Real Time (25 ± 2°C / 60% RH ± 5%) for 72 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence / Comparative Analysis of their applied product against Reference product Carboplatin concentrate for Solution for Infusion, 450mg/45ml (B. No. 21NC0022, Mg. By Accord Healthcare Limited).
	Analytical method validation / verification of product	Firm has submitted Analytical Method Validation Reports for their applied product.
	Container closure system of the drug product	50ml amber coloured USP Type I glass vials with having 20mm serum laminated chlorobutyl rubber stopper and sealed with 20mm Light Blue coloured flip-off seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30° C ± 2° C 75% ± 5% RH for 36 Months.

Batch No.	Mfg. Date
CBPI00518C	Sep. 2018
CBPI00618C	Sep. 2018

		CBPI00718C	Sep. 2018

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm: -

i. The Firm has submitted **Scanned Copy** of legalized & notarized CoPP Certificate No. 4429584/TS/2023 dated 08-08-2023 issued by Drugs Control Administration, Telangana State for Carboplatin Concentrate for Solution for Infusion BP 450mg/45ml (CARBO SPAL-L 450), valid up to 05/10/2025. **Please provide Original legalized & notarized document for the same.**

ii. Finished product specifications have been claimed as "BP" whereas in section 3.2.P.2.1 Specifications No. FPIN018-S-02, Effective 30-04-2021, Reference for Identification, Assay and Related Substances by HPLC has been claimed as "In-House". Please justify.

iii. Firm has submitted **Photocopy** of notarized 'Authorization Letter' issued by M/s SP Accure Labs Private Limited. **Please provide Original notarized document for the same.**

iv. **"Annex 1"** claimed to be enclosed with above 'Authorization Letter' has not been submitted in application dossier.

v. The name of firm as mentioned on 'Authorization Letter' and information provided by FPP Manufacturer throughout the application dossier states its name as "**M/s SP Accure Labs Private Limited".** However, the name of FPP Manufacturer as evident from documents issued by Regulatory Authority of country of origin specifies it as **M/s SPAL Private Limited.** Please justify / provide supporting documents for change of name to 'M/s SP Accure Labs Private Limited' issued by concerned authorities.

vi. The label claim has been mentioned throughout the application dossier as "Each **ml Vial** contains…", whereas the proposed pack size is **45ml Vial**. Please justify.

Decision of 333rd Meeting: Deferred for submission of reply to above cited shortcomings.

Remarks of Evaluator: The firm has submitted as follows:

Shortcomings	Firm's Submission
The Firm has submitted **Scanned Copy** of legalized & notarized CoPP Certificate No. 4429584/TS/2023 dated 08-08-2023 issued by Drugs Control Administration, Telangana State for Carboplatin Concentrate for Solution for Infusion BP 450mg/45ml (CARBO SPAL-L 450), valid up to 05/10/2025. **Please provide Original legalized & notarized document for the same.**	**Scanned Copy has been submitted again.**
Finished product specifications have been claimed as "BP" whereas in section 3.2.P.2.1 Specifications No. FPIN018-S-02, Effective 30-04-2021, Reference for Identification, Assay and Related Substances by HPLC has been claimed as "In-House". Please justify.	Firm has submitted that all the tests of BP have been included in Finished Product Specifications with **Additional In-house Testing Specs.**
Firm has submitted **Photocopy** of notarized 'Authorization Letter' issued by M/s SP Accure Labs Private Limited. **Please provide Original notarized document for the same.**	**Scanned Copy has been submitted again.**

"Annex 1" claimed to be enclosed with above 'Authorization Letter' has not been submitted in application dossier.	**Scanned Copy has been submitted.**
The name of firm as mentioned on 'Authorization Letter' and information provided by FPP Manufacturer throughout the application dossier states its name as "**M/s SP Accure Labs Private Limited".** However, the name of FPP Manufacturer as evident from documents issued by Regulatory Authority of country of origin specifies it as **M/s SPAL Private Limited.** Please justify / provide supporting documents for change of name to 'M/s SP Accure Labs Private Limited' issued by concerned authorities.	Firm has submitted **a Photocopy of Letter** vide No. L.Dis.No. 22156/E(M)/TS/2017 dated 8/11/2017 from Drug Control Administration, Telangana, **stating that the company name (SP Accure Labs Pvt. Ltd and SPAL Private Limited) is one and the same. Further stating full form of SPAL is SP Accure Labs**.
The label claim has been mentioned throughout the application dossier as "Each **ml Vial** contains…", whereas the proposed pack size is **45ml Vial**. Please justify.	Firm has mentioned Label Claim as: **Each mL vial contains:** Carboplatin … 10mg (BP Specs) **While our claimed vial is 45mL (total filled volume in 1's vial).**

Decision: Approved as per Policy for inspection of Manufacturer abroad.

The firm shall submit the following before issuance of registration letter: -

- **Fee for pre-registration correction of Label Claim as:**
  Each 45mL vial contains:
  Carboplatin … 10mg
  (BP Specs)

- **Original Notarized Certificate of Pharmaceutical Product (CoPP).**
- **Original Notarized Letter of Authorization (LoA).**

Agenda Item No. 03:
Routine applications submitted on Form 5F for local manufacturing (Human).

1041.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33961 dated 24-11-2022
	Details of fee submitted	PKR 75,000/- dated 17-11-2022 Challan / Receipt # 61143685526
	The proposed proprietary name / brand name	**RISON 0.5mg Oral Disintegrating Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrated Tablet contains: Risperidone…0.5mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Tablets (USFDA Approved)
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR /AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd. was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted
v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1042.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33960 dated 24-11-2022
	Details of fee submitted	PKR 30,000/- dated 17-11-2022 Challan / Receipt # 958126600
	The proposed proprietary name / brand name	**RISON 1mg Oral Disintegrating Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrated Tablet contains: Risperidone…1mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Tablets (USFDA Approved)
	For generic drugs (me-too status)	Wizen Flash Tablets 1mg of M/s Werrick Pharmaceuticals.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR /AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd. was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted

v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1043.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33962 dated 24-11-2022
	Details of fee submitted	PKR 30,000/- dated 17-11-2022 Challan / Receipt # 344384956599
	The proposed proprietary name / brand name	**RISON 2mg Oral Disintegrating Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrated Tablet contains: Risperidone…2mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Tablets (USFDA Approved)
	For generic drugs (me-too status)	Wizen Flash Tablets 2mg of M/s Werrick Pharmaceuticals.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd.

	/AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted
v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1044.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35672 dated 08-12-2022
	Details of fee submitted	PKR 30,000/- dated 17-11-2022 Challan / Receipt # 62510117015
	The proposed proprietary name / brand name	**RISON 3mg Oral Disintegrating Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrated Tablet contains: Risperidone…3mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Tablets (USFDA Approved)
	For generic drugs (me-too status)	Wizen Flash Tablets 3mg of M/s Werrick Pharmaceuticals.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR /AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd. was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted
v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1045.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34709 dated 30-11-2022
	Details of fee submitted	PKR 30,000/- dated 17-11-2022 Challan / Receipt # 16485139880
	The proposed proprietary name / brand name	**RISON 4mg Oral Disintegrating Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrated Tablet contains: Risperidone…4mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Tablets (USFDA Approved)
	For generic drugs (me-too status)	Wizen Flash Tablets 4mg of M/s Werrick Pharmaceuticals.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR /AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd. was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted
v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1046.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.**

	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Plot No. 44-45- B Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5255 dated 23-02-2023
	Details of fee submitted	PKR 30,000/- dated 10-02-2023 Challan / Receipt # 04658878888
	The proposed proprietary name / brand name	**RISON 1mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Risperidone…1mg
	Pharmacotherapeutic Group of (API)	N05AX08, Other antipsychotics.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	RISPERDAL Oral Solution (USFDA Approved)
	For generic drugs (me-too status)	Risperiget Oral Solution 1mg/ml of M/s Getz Pharma (Pvt.) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of manufacturing facility (Section Approval letter from Licensing division for Tablet section).	Firm have submitted copy of letter for grant of additional / revised section / facility dated 30th September 2021. The letter mentions Tablet (General) – Revised section.
ii.	3.2.S.4.3 Analytical Method Verification Report No. AMVR /AS/050/00 is from Nutra Specialities Private Limited. Please clarify.	Firm have submitted that Venkata Narayana Active Ingredients Pvt. Ltd. was previously named as Neutra Specialities Private Limited. Copy of Certificate of Incorporation pursuant to change of name have been submitted.
iii.	Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate valid for 03 years from 19.09.2023 has been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted

v.	Please provide reference of previous approval of applications with stability study data of the firm (if any).	OLAGEN OD Tablets (Olanzapine) 5mg, 10mg and 20mg discussed in 331st Registration Board meeting.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1047.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 38212 dated 28-11-2022
	Details of fee submitted	PKR 75,000/- dated 07-11-2022 Challan / Receipt # 92127778805
	The proposed proprietary name / brand name	**ZIBES-A 5+5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Bisoprolol fumarate … 5mg Amlodipine besilate 6.95mg equivalent to Amlodipine … 5mg
	Pharmacotherapeutic Group of (API)	C07FB07, Beta blocking agents and calcium channel blockers.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Concor AMLO 5mg/5mg Tablets (Austrian Medicines and Medical Devices Agency Approved)
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	The enclosed GMP Certificate of API Manufacturer (of **Amlodipine besilate**) is due to be expired on 26/05/2024. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of	Firm have submitted copy of Retention of License (from 08/04/2020 to 07/04/2025) along with API approval list issued by Food and Drugs Control Administration, Gujarat State, India.

	country of origin along with API Approval List.	
ii.	Sign & stamp of AD (I&E) DRAP Karachi on enclosed copy of Commercial Invoice No. EXP/21-22/027 dated 17th May 2021 (for **Amlodipine besilate**) are not visible. Please provide a legible copy of the same.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1048.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36504 dated 15-12-2022
	Details of fee submitted	PKR 75,000/- dated 07-11-2022 Challan / Receipt # 51324603
	The proposed proprietary name / brand name	**ZIBES-A 5+10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Bisoprolol fumarate … 5mg Amlodipine besilate 13.9mg equivalent to Amlodipine … 10mg
	Pharmacotherapeutic Group of (API)	C07FB07, Beta blocking agents and calcium channel blockers.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Concor AMLO 5mg/10mg Tablets (Austrian Medicines and Medical Devices Agency Approved)
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response

i.	The enclosed GMP Certificate of API Manufacturer (of **Amlodipine besilate**) is due to be expired on 26/05/2024. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin along with API Approval List.	Firm have submitted copy of Retention of License (from 08/04/2020 to 07/04/2025) along with API approval list issued by Food and Drugs Control Administration, Gujarat State, India.
ii.	Sign & stamp of AD (I&E) DRAP Karachi on enclosed copy of Commercial Invoice No. EXP/21-22/027 dated 17th May 2021 (for **Amlodipine besilate**) are not visible. Please provide a legible copy of the same.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1049.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36505 dated 15-12-2022
	Details of fee submitted	PKR 75,000/- dated 07-11-2022 Challan / Receipt # 976906267
	The proposed proprietary name / brand name	**ZIBES-A 10+5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Bisoprolol fumarate … 10mg Amlodipine besilate 6.95mg equivalent to Amlodipine … 5mg
	Pharmacotherapeutic Group of (API)	C07FB07, Beta blocking agents and calcium channel blockers.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Concor AMLO 10mg/5mg Tablets (Austrian Medicines and Medical Devices Agency Approved)
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	The enclosed GMP Certificate of API Manufacturer (of **Amlodipine besilate**) is due to be expired on 26/05/2024. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin along with API Approval List.	Firm have submitted copy of Retention of License (from 08/04/2020 to 07/04/2025) along with API approval list issued by Food and Drugs Control Administration, Gujarat State, India.
ii.	Sign & stamp of AD (I&E) DRAP Karachi on enclosed copy of Commercial Invoice No. EXP/21-22/027 dated 17th May 2021 (for **Amlodipine besilate**) are not visible. Please provide a legible copy of the same.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1050.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 38213 dated 28-12-2022
	Details of fee submitted	PKR 75,000/- dated 07-11-2022 Challan / Receipt # 285168043
	The proposed proprietary name / brand name	**ZIBES-A 10+10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Bisoprolol fumarate … 10mg Amlodipine besilate 13.9mg equivalent to Amlodipine … 10mg
	Pharmacotherapeutic Group of (API)	C07FB07, Beta blocking agents and calcium channel blockers.
	Reference to Finished product specifications	Innovator's Specifications

	The status in reference regulatory authorities	Concor AMLO 10mg/10mg Tablets (Austrian Medicines and Medical Devices Agency Approved)
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	The enclosed GMP Certificate of API Manufacturer (of **Amlodipine besilate**) is due to be expired on 26/05/2024. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin along with API Approval List.	Firm have submitted copy of Retention of License (from 08/04/2020 to 07/04/2025) along with API approval list issued by Food and Drugs Control Administration, Gujarat State, India.
ii.	Sign & stamp of AD (I&E) DRAP Karachi on enclosed copy of Commercial Invoice No. EXP/21-22/027 dated 17th May 2021 (for **Amlodipine besilate**) are not visible. Please provide a legible copy of the same.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1051.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3139 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 331736067
	The proposed proprietary name / brand name	**MYTAKRO 0.5mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate… 0.5mg

	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immuno-modulating Agents, Calcineurin inhibitors.
	Reference to Finished product specifications	USP Specs
	The status in reference regulatory authorities	VIVADEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC MHRA Approved.
	For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

- 2.3.P.1.(a) Description of the FPP has been mentioned as '*White to off white color powder filled in **yellow body white cap** hard gelatin capsule shell*' as well as '*White to off white color powder filled in **white body white cap** hard gelatin capsule shell*'. Please justify.
- 3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).
- Avg. Weight has been mentioned as 100mg $\pm$ 5%, 150mg $\pm$ 5% as well as 100mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.
- Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.
- Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.
- Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till **29-01-2022.**
- Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.

Decision:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

1052.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3140 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 29967435581
	The proposed proprietary name / brand name	**MYTAKRO 1mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate… 1mg

	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immuno-modulating Agents, Calcineurin inhibitors.
	Reference to Finished product specifications	USP Specs
	The status in reference regulatory authorities	VIVADEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC MHRA Approved.
	For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

- 3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).
- Avg. Weight has been mentioned as 100mg ± 5%, 150mg ± 5% as well as 100mg ± 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.
- Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.
- Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.
- Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till **29-01-2022.**
- Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.

Decision:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

1053.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3122 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 759489500668
	The proposed proprietary name / brand name	**MYTAKRO 5mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate… 5mg
	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immuno-modulating Agents, Calcineurin inhibitors.
	Reference to Finished product specifications	USP Specs

	The status in reference regulatory authorities	VIVADEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC MHRA Approved.
	For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

- 3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).
- Avg. Weight has been mentioned as 215mg ± 5% as well as 215mg ± 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.
- Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.
- Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.
- Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till **29-01-2022.**
- Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.

Decision:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

1054.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5260 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 1415475365
	The proposed proprietary name / brand name	**TUGLIF-M 2.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 2.5mg Metformin Hydrochloride … 1000mg
	Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications

	The status in reference regulatory authorities	SEGLUROMET Tablet 2.5/1000mg (USFDA Approved).
	For generic drugs (me-too status)	LOZGIL-M Tablet 2.5/1000mg of M/s Genix Pharma (Private) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Admistration, China.
ii.	**Metformin Hydrochloride:** Please provide valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid until **12-03-2024.**	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06th Month (Accelerated) testing interval from initial test results of Ertugliflozin, Batch No. 058B22. Please justify.	Firm have submitted justification as follows: - • When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. • In the case of small batch sizes, it is important to acknowledge that the results obtained from the stablility testing may not fully reflect the true stability profile of the product. • Despite the challenges, all other parameters were satisfactory that shows variation is not as significant.
iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22nd February, 2023.

Decision: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accalerated stability studies of Batch no. 058B22 decided to defer the case for submission of stability studies of newly formulated batches.

1055.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**

	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5259 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 4043535505
	The proposed proprietary name / brand name	**TUGLIF-M 7.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 7.5mg Metformin Hydrochloride … 1000mg
	Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	SEGLUROMET Tablet 7.5/1000mg (USFDA Approved).
	For generic drugs (me-too status)	LOZGIL-M Tablet 7.5/1000mg of M/s Genix Pharma (Private) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Admistration, China.
ii.	**Metformin Hydrochloride:** Please provide valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.

	origin. The enclosed GMP Certificate was valid until **12-03-2024.**	
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06th Month (Real Time) testing interval from initial test results of Metformin, Batch No. 060B22. Please justify.	Firm have submitted justification as follows: - • When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. • In the case of small batch sizes, it is important to acknowledge that the results obtained from the stablility testing may not fully reflect the true stability profile of the product. • Despite the challenges, all other parameters were satisfactory that shows variation is not as significant.
iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22nd February, 2023.

Decision: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accalerated stability studies of Batch no. 060B22 decided to defer the case for submission of stability studies of newly formulated batches.

1056.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot No. 44 A-B, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot No. 44 A-B, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 46 dated 02 JAN 2023
	Details of fee submitted	PKR 30,000/- dated 13-12-2022 Challan / Receipt # 4605638340
	The proposed proprietary name / brand name	**ERASTU 15/100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 15mg Sitagliptin (as Phosphate Monohydrate) … 100mg
	Pharmacotherapeutic Group of (API)	A10BD24, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory	STEGLUJAN Tablet 15/100mg (EMA Approved).

	authorities	
	For generic drugs (me-too status)	ERTUVIA-S Tablets 15/100mg of M/s Ferozsons Laboratories Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

- **Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.
- **Sitagliptin Phosphate Monohydrate:** Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Medical and Chemical Industry Association is not the concerned regulatory authority of country of origin.
- 3.2.S.7 **Sitagliptin Phosphate Monohydrate:** Real Time Stability Study Data have been submitted for 06 Months only whereas claimed Shelf Life of API, as evident from submitted COA, is 03 Years. Please justify / provide complete data as per claimed shelf life.
- The Supporting Data of Pharmaceutical Equivalence and CDP in section 3.2.P.2.2.1 as well as Analytical Method Validation in section 3.2.P.5.3 and Stability Studies Data in section 3.2.P.8 has been submitted for "**ErtuSita 15-100mg Tablet**" whereas application dossier has been submitted for "ERASTU 15/100mg Tablet". Please clarify.
- In section 3.2.P.2.2.1 and in submitted Trial Manufacturing Records, it has been mentioned that 'Tab Coat TC-116-280001, **Yellow**' has been used for Film Coating, whereas the Physical appearance / colour of the Tablet has been described as '**White**' in Comparative Dissolution Profile and Stability Study Data Results of all 03 Batches. Please justify with supporting evidence.
- 3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for **06th Month Testing Interval** of all 03 Trials.

Decision:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

1057.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot No. 44 A-B, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot No. 44 A-B, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36502 dated 15 DEC 2022
	Details of fee submitted	PKR 30,000/- dated 10-11-2022 Challan / Receipt # 0318977794
	The proposed proprietary name / brand name	**ERASTU 5/100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 5mg Sitagliptin (as Phosphate Monohydrate) … 100mg

	Pharmacotherapeutic Group of (API)	A10BD24, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	STEGLUJAN Tablet 5/100mg (EMA Approved).
	For generic drugs (me-too status)	ERTUVIA-S Tablets 5/100mg of M/s Ferozsons Laboratories Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

- **Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.
- **Sitagliptin Phosphate Monohydrate:** Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Medical and Chemical Industry Association is not the concerned regulatory authority of country of origin.
- 3.2.S.7 **Sitagliptin Phosphate Monohydrate:** Real Time Stability Study Data have been submitted for 06 Months only whereas claimed Shelf Life of API, as evident from submitted COA, is 03 Years. Please justify / provide complete data as per claimed shelf life.
- The Supporting Data of Pharmaceutical Equivalence and CDP in section 3.2.P.2.2.1 as well as Analytical Method Validation in section 3.2.P.5.3 and Stability Studies Data in section 3.2.P.8 has been submitted for "**ErtuSita 5-100mg Tablet**" whereas application dossier has been submitted for "ERASTU 5/100mg Tablet". Please clarify.
- 3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for **06th Month Testing Interval** of all 03 Trials.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Agenda of Evaluator PEC-XXIII

Case no. 01 Registration applications of categories to be considered on priority

b. Export facilitation

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 26-05-2023 has informed that M/s Scilife Pharma Pvt Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi has achieved benchmark of USD 100,000 during fiscal year 2021-2022 and requested for priority consideration of following molecules:

1058.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 29/2021-DRAP(K) issued on the basis of inspection conducted on 01-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 18-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29611 dated 18-10-2022.
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 73155335581
	The proposed proprietary name / brand name	**TUGLIF 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as Ertugliflozin L-Pyroglutamic Acid…5mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Round film coated tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 14's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 5mg (USFDA, TGA Australia Approved)
	For generic drugs (me-too status)	Ertuget Tablet 5mg of M/s Getz Pharma Pvt Ltd, (Reg.No. 110368) & Ertuvia Tablet 5mg of M/s Ferozsons Laboratories, Ltd. (Reg.No. 110362)
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Ertuvia Tablet 5mg of M/s Ferozsons Laboratories, Ltd. (Reg.No. 110362). Firm has submitted CDP results of their product against the comparator product Ertuvia Tablet 5mg in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.		
API Lot No.	L-IG-20211005-D01-IG06-03		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	007B22	008B22	009B22
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	02-02-2022	02-02-2022	02-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Tablets Glusimet XR 50/500mg and Tablets

		Glusimet XR 50/1000mg, for which the inspection was conducted on 16-07-2020 and the report was presented in 296th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR compliant. ii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 01-12-2021 specifying import of 1kg of Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin or CEP certificate shall be submitted as the already submitted GMP certificate of drug substance manufacturer was valid till 23-08-2023 and cannot be verified from database of country of origin.	Firm has submitted copy of API manufacturer's License No. 20150233 valid till 17-11-2027 issued by Liaoning Provincial Food and Drug Administration.
2.	**2.3.R.1.1**	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 shall be submitted.	Submitted.
3.	**3.2.S.4.3**	Raw data and chromatograms for analytical method verification and analytical method verification protocol of raw material by drug product manufacturer shall be submitted.	Submitted.
4.	**3.2.S.7**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions.	Submitted.
5.	**3.2.P.2.2.1 & 3.2.P.5**	Justification shall be submitted regarding the acceptance criteria of disintegration test i.e. NMT 30 minutes in the light of review literature of innovator brand approved in TGA/USFDA since the review report of innovator brand reveals that disintegration limits for the	Disintegration time limit has been revised in the light of review literature of innovator brand.

		reference product shall be more stringent than those given in European Pharmacopeia for coated tablets.	

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.
Registration Board further decided that registration letter will be issued after submission of following:
Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.

1059.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma Pvt Ltd.** **Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 29/2021-DRAP(K) issued on the basis of inspection conducted on 01-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 18-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29612 dated 18-10-2022.
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 495872830927
	The proposed proprietary name / brand name	**TUGLIF 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as Ertugliflozin L-Pyroglutamic Acid…15mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Round film coated tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 14's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 15mg (USFDA, TGA Australia Approved)
	For generic drugs (me-too status)	Ertuget Tablet 15mg of M/s Getz Pharma Pvt Ltd, (Reg.No. 110369) & Ertuvia Tablet 15mg of M/s Ferozsons Laboratories, Ltd. (Reg.No. 110363)

	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro Tablet 15mg of Merck Sharp & Dohme Corp. Firm has submitted CDP results of their product against the innovator's product Steglatro Tablet 15mg in 3 dissolution medi. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng	

	County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.		
API Lot No.	L-IG-20211005-D01-IG06-03		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	010B22	011B22	012B22
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	02-02-2022	02-02-2022	02-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Tablets Glusimet XR 50/500mg and Tablets Glusimet XR 50/1000mg, for which the inspection was conducted on 16-07-2020 and the report was presented in 296th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR compliant. ii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 01-12-2021 specifying import of 1kg of Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin or CEP certificate shall be submitted as the already submitted GMP	Firm has submitted copy of API manufacturer's License No. 20150233 valid till 17-11-2027 issued by Liaoning Provincial Food and Drug Administration.

		certificate of drug substance manufacturer was valid till 23-08-2023 and cannot be verified from database of country of origin.	
2.	**2.3.R.1.1**	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 shall be submitted.	Submitted.
3.	**3.2.S.4.3**	Raw data and chromatograms for analytical method verification and analytical method verification protocol of raw material by drug product manufacturer shall be submitted.	Submitted.
4.	**3.2.S.7**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions.	Submitted.
5.	**3.2.P.2.2.1 & 3.2.P.5**	Justification shall be submitted regarding the acceptance criteria of disintegration test i.e. NMT 30 minutes in the light of review literature of innovator brand approved in TGA/USFDA since the review report of innovator brand reveals that disintegration limits for the reference product shall be more stringent than those given in European Pharmacopeia for coated tablets.	Disintegration time limit has been revised in the light of review literature of innovator brand.

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Registration Board further decided that registration letter will be issued after submission of following:

Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.

1060.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 29/2021-DRAP(K) issued on the basis of inspection conducted on 01-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 18-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34700 dated 30-11-2022.

	Details of fee submitted	PKR 30,000/- Deposit Slip No. 29452008614
	The proposed proprietary name / brand name	**TUGLIF-S 5/100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as Ertugliflozin L-Pyroglutamic Acid…5mg Sitagliptin Phosphate Monohydrate as Sitagliptin…100mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, Combinations of oral blood glucose lowering drugs
	Pharmaceutical form of applied drug	Round film coated tablet plain from both sides
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 28's & 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglujan Tablet 5/100mg (USFDA Approved)
	For generic drugs (me-too status)	Trevia R2 Tablet 5/100mg of M/s Getz Pharma Pvt Ltd (Reg. No. 110366)
	Name and address of API manufacturer.	Ertugliflozin: Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China. Sitagliptin: Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Ertugliflozin LPGA: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Sitagliptin Phosphate Monohydrate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Trevia R2 Tablet 5/100mg of M/s Getz Pharma Pvt Ltd (Reg. No. 110366). Firm has submitted CDP results of their product against the comparator product Trevia R2 Tablet 5/100mg in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.		
API Lot No.	Ertugliflozin LPGA: L-IG-20211005-D01-IG06-03 Sitagliptin: H-GWC-20201223-D04-GWC04-11		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	029B22	031B22	032B22
Batch Size	5000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	24-03-2022	24-03-2022	24-03-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Tablets Glusimet XR 50/500mg and Tablets Glusimet XR 50/1000mg, for which the inspection was conducted on 16-07-2020 and the report was presented in 296th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR compliant. ii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 01-12-2021 specifying import of 1kg of Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi. Sitagliptin Phosphate Monohydrate: Firm has submitted copy of commercial invoice cleared on 16-06-2021 specifying import of 200kg of Sitagliptin Phosphate Monohydrate. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature monitoring of real time and accelerated stability chambers for one month only.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin or CEP certificate shall be submitted as the already submitted GMP certificate of Ertugliflozin LPGA drug substance manufacturer was valid till 23-08-2023 and cannot be verified from database of country of origin.	Copy of valid DML submitted.
2.	**2.3.R.1.1**	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 shall be submitted.	Submitted
3.	**3.2.S.4.3**	Analytical method verification protocol, report and supportive data (including chromatograms) for both raw materials by drug product manufacturer shall be submitted, as the already submitted report is for finished drug instead of raw materials.	Submitted

4.	**3.2.S.7**	Long term stability studies of both drug substances shall be submitted as per Zone-IVa conditions.	Submitted
5.	**3.2.P.2.2.1 & 3.2.P.5**	Justification shall be submitted regarding the acceptance criteria of disintegration test i.e. NMT 30 minutes in the light of review literature of innovator brand approved in TGA/USFDA since the review report of innovator brand reveals that disintegration limits for the reference product shall be more stringent than those given in European Pharmacopeia for coated tablets.	Current specifications meet pharmacopoeia requirement however, for stringent limit, the specifications are revised.
6.	**3.2.P.8**	Documents for the procurement of Sitagliptin API with approval from DRAP shall be submitted.	Submitted.
7.	**3.2.P.8**	Justify the difference in batch size of stability batches.	Applicant has submitted following justification: "As per the Guidance Document for Submission of Application on Form 5-F (CTD) for Registration of Pharmaceutical Drug Products for Human Use one of the criteria for selection of size of batches for OSDs is 5000 units following which we have manufactured our first trial batch on 5000 units However, keeping in consideration that we have a diversity of products containing Ertugliflozin ie. Tuglif Tablet range, Tuglif-M Tablet range & Tuglif-S Tablet range we have reduced the batch size of 2 batches to 3000 units after complete calculation that it would be sufficient enough to perform complete testing till the claimed shelf life However, based on the query raised on subject product, we assure to keep it similar in future product developments."
8.	**3.2.P.8**	Record of Digital data logger for temperature and *humidity monitoring* of stability chambers (real time and accelerated) shall be provided for the at least 6 months during the course of stability studies.	Submitted.

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **Registration Board further decided that registration letter will be issued after submission of following:** **Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.**		
1061.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma Pvt Ltd.** **Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. 29/2021-DRAP(K) issued on the basis of inspection conducted on 01-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 18-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34701 dated 30-11-2022.
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 6330474107
	The proposed proprietary name / brand name	**TUGLIF-S 15/100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as Ertugliflozin L-Pyroglutamic Acid…15mg Sitagliptin Phosphate Monohydrate as Sitagliptin…100mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, Combinations of oral blood glucose lowering drugs
	Pharmaceutical form of applied drug	Round film coated tablet plain from both sides
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 28's & 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglujan Tablet 15/100mg (USFDA Approved)
	For generic drugs (me-too status)	Trevia R2 Tablet 15/100mg of M/s Getz Pharma Pvt Ltd (Reg. No. 110367)
	Name and address of API manufacturer.	Ertugliflozin: Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.

		Sitagliptin: Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Ertugliflozin LPGA: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Sitagliptin Phosphate Monohydrate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Trevia R2 Tablet 15/100mg of M/s Getz Pharma Pvt Ltd (Reg. No. 110367). Firm has submitted CDP results of their product against the comparator product Trevia R2 Tablet 15/100mg in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.		
API Lot No.	Ertugliflozin LPGA: L-IG-20211005-D01-IG06-03 Sitagliptin: H-GWC-20201223-D04-GWC04-11		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	030B22	033B22	034B22
Batch Size	5000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	24-03-2022	24-03-2022	24-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Tablets Glusimet XR 50/500mg and Tablets Glusimet XR 50/1000mg, for which the inspection was conducted on 16-07-2020 and the report was presented in 296th meeting of Registration Board. The report confirms following points: iii. The HPLC software is 21CFR compliant. iv. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 01-12-2021 specifying import of 1kg of Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi. Sitagliptin Phosphate Monohydrate: Firm has submitted copy of commercial invoice cleared on 16-06-2021 specifying import of 200kg of

		Sitagliptin Phosphate Monohydrate. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin or CEP certificate shall be submitted as the already submitted GMP certificate of Ertugliflozin LPGA drug substance manufacturer was valid till 23-08-2023 and cannot be verified from database of country of origin.	Copy of valid DML submitted.
2.	**2.3.R.1.1**	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 shall be submitted.	Submitted
3.	**3.2.S.4.3**	Analytical method verification protocol, report and supportive data (including chromatograms) for both raw materials by drug product manufacturer shall be submitted, as the already submitted report is for finished drug instead of raw materials.	Submitted
4.	**3.2.S.7**	Long term stability studies of both drug substances shall be submitted as per Zone-IVa conditions.	Submitted
5.	**3.2.P.2.2.1 & 3.2.P.5**	Justification shall be submitted regarding the acceptance criteria of disintegration test i.e. NMT 30 minutes in the light of review literature of innovator brand approved in TGA/USFDA since the review report of innovator brand reveals that disintegration limits for the reference product shall be more stringent than those given in European Pharmacopeia for coated tablets.	Current specifications meet pharmacopoeia requirement however, for stringent limit, the specifications are revised.
6.	**3.2.P.8**	Documents for the procurement of Sitagliptin API with approval from DRAP shall be submitted.	Submitted.
7.	**3.2.P.8**	Justify the difference in batch size of stability batches.	Applicant has submitted following justification: "As per the Guidance Document for Submission of Application on Form 5-

				F (CTD) for Registration of Pharmaceutical Drug Products for Human Use one of the criteria for selection of size of batches for OSDs is 5000 units following which we have manufactured our first trial batch on 5000 units However, keeping in consideration that we have a diversity of products containing Ertugliflozin ie. Tuglif Tablet range, Tuglif-M Tablet range & Tuglif-S Tablet range we have reduced the batch size of 2 batches to 3000 units after complete calculation that it would be sufficient enough to perform complete testing till the claimed shelf life However, based on the query raised on subject product, we assure to keep it similar in future product developments."
	8.	**3.2.P.8**	Record of Digital data logger for temperature and *humidity monitoring* of stability chambers (real time and accelerated) shall be provided for the at least 6 months during the course of stability studies.	Submitted.

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.
Registration Board further decided that registration letter will be issued after submission of following:
Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.

c. Import applications of priority categories defined by Registration Board in its 257th meeting

i. Human (Form5F)

1062.	**Name, address of Applicant / Importer**	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Details of Drug Sale License of importer	**License No.: 05-352-0065-031159D** **Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity:** 21-05-2027 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	**M/s SPAL Private, Ltd,** Plot No. 12, Biotech Park, Phase-II, Lalgadi-Malakpet (V), Shamirpet (M),

		Medchal-Malkagiri District, Telangana State- 500101, India.
	Name, address of manufacturer(s)	**M/s SPAL Pvt, Ltd,** Plot No. 12, Biotech Park, Phase-II, Laalgadi Malakpet (V), Shamirpet (M), Medchal-Malkagiri District, Telangana State- 500101, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of legalized CoPP certificate (No. 2858071/TS/2022) dated 06-05-2022 issued by Drugs Control Administration, Vengalraonagar, Hyderabad, India for BSLF SPAL-L 60 Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 01 year. Validity of the CoPP is till 22-06-2024. **The name of importing country on CoPP is mentioned as Pakistan.** **GMP certificate:** Firm has submitted copy of legalized **GMP** certificate (L.Dis.No.44736/STORES/2021) dated 30-01-2021 issued by Drugs Control Administration, Government of Telangana, Hyderabad, India in name of M/s SPAL Pvt, Ltd, Plot No. 12, Biotech Park, Phase-II, Laalgadi Malakpet (V), Shamirpet (M), Medchal-Malkagiri District, Telangana State-500101. The certificate is valid for three years from the date of issue in respect of four products.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of notarized Authorization letter from M/s SP Accure Labs Pvt Ltd Plot No. 12, Biotech Park, Phase-II, Laalgadi Malakpet (V), Shamirpet (M), Medchal-Malkagiri District, Telangana State- 500101, India which authorises M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore as exclusive distributor for products manufactured by M/s SP Accure Labs Pvt Ltd. The Authorization letter is dated 07-06-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No 18244 dated 19-07-2023
	Details of fee submitted	Rs.75,000/- dated 04-07-2023
	The proposed proprietary name / brand name	**BSLF SPAL-L 60 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml vial contains 6mg of Busulfan
	Pharmaceutical form of applied drug	Concentrate for solution for IV infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic agent (L01AB01)
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10ml x 1's
	Proposed unit price	As per PRC/SRO
	The status in reference regulatory authorities	Busulfex (Busulfan) Injection, for intravenous use USFDA Approved Busulfan 6 mg/ml concentrate for solution for infusion by Accord Healthcare, UK (MHRA Approved).
	For generic drugs (me-too status)	Not applicable since the applied product is a new drug
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shilpa Medicare Limited, Unit II, Raichur Industrial Growth Centre, Plot No.s 33, 33A, 40-47, Wadloor Road, Chicksugar Village, Raichur, Karnataka, 584134, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Busulfex Injection 60mg/10ml by Otsuka America Pharmaceutical, MD 20850.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	10mL tubular clear 20mm collar flat bottom vial (USP Type I) with 20mm grey flurotech coated chlorobutyl rubber stopper and sealed with 20mm aluminium flip off seal of purple color.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5ºC ±3ºC. The real time stability study data for 3 batches is for 24 months only. In use stability study was performed with diluents 0.9% sodium chloride (USP) and 5% dextrose (USP) for safety assurance prior to IV infusion.

Remarks of Evaluator [xxiii]:

Sr. No.	Sections/ Modules	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.4.1**	Applicant has applied under New Drug Product with PKR 75,000/- according to Module 1.4.1 and fee challan whereas the generic drug in the applied dosage form has already been approved by the RB in its 324th meeting. Submit PKR 75,000 differential fee.	Our applied product is a "New Drug Product" The product Busulfan Injection 60mg is approved in 324th minutes of RB but the registration letter has not been issued to date. So our applied product is a New Drug Product.
2.	**1.3.3**	Copy of legalized CoPP is submitted. Original, Valid, legalized & notarized CoPP shall be submitted.	**CoPP:** Firm has again submitted ***scanned copy*** of legalized CoPP certificate (No. 4429589/TS/2023) dated 08-08-2023 issued by Drugs Control Administration, Vengalraonagar, Hyderabad, India for BSLF SPAL-L 60 Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 01 year. Validity of the CoPP is till 16-10-2025.
3.		• Sole agency agreement letter between importer and manufacturer abroad is a copy. Original, notarized, valid sole agency agreement shall be submitted. • Sole agency agreement is between M/s SP Accure Labs Private Ltd	• Copy of Sole agency agreement letter has been submitted again. • Firm has submitted a Photocopy of Letter vide No. L.Dis.No. 22156/E(M)/TS/2017 dated 8/11/2017 from

			and M/s Revive Healthcare whereas the name of principal manufacturer on CoPP and GMP certificate is M/s SPAL Pvt Ltd. Clarify the legal name of the manufacturer abroad with documentary evidence and submit CoPP/sole agency agreement accordingly, as the case may be.	Drug Control Administration, Telangana, stating that the company name (SP Accure Labs Pvt. Ltd and SPAL Private Limited) is one and the same. Further stating that full form of SPAL is SP Accure Labs.
	4.	**3.2.P.1**	Details of diluent including brand name, manufacturer's name, specifications, pack size, container closure system and registration number shall be submitted.	We have not applied the product as combo-pack or with accompanying diluent. So required information regarding this section is not needed
	5.	**3.2.S.5 & 3.2.P.6**	Drug substance complies USP and IH specifications whereas the reference standard used by drug substance manufacturer is EP Reference standard. Justify.	Assay limit of Busulfan in monograph of EP is more stringent than USP. So substance manufacturer (Shilpa Medicare) procured and used EP reference standard for testing.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Registration Board further decided that registration letter will be issued after submission of following:
i. Original, Valid, CoPP,
ii. Original, Valid, notarized letter of authorization to I&V Section,
iii. Differential fee of Rs. 75000/- as the applied product is not yet registered in Pakistan.

Case no. 02 Registration applications for local manufacturing of (Human) drugs

a. New cases (Form 5F)

1063.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of report for DML renewal based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27894 dated 03-10-2022.

	Details of fee submitted	PKR 30,000/- DS No. 061179508
	The proposed proprietary name / brand name	**ERTUNEXT 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid…19.44mg eq. to 15mg of Ertugliflozin
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Oblong biconvex film coated tablet with score line on one side
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 20's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 15mg (USFDA Approved)
	For generic drugs (me-too status)	Ertuvia Tablet 15mg of M/s Ferozsons Laboratories Ltd (Reg. No. 110363)
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ±

		5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro 15mg Tablet by MSD Sub Merck. Firm has submitted CDP results of their product against the innovator's product Steglatro 15mg Tablet in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.		
API Lot No.	L-IG-20211005-D01-IG06-03		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0004TBD	T-0005TBD	T-0006TBD
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	08-06-2022	08-06-2022	08-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.P.5.1**	Specifications do not include content of Ertugliflozin LPGA and LPGA. Justify.	Applicant has submitted revised specifications. *Fee shall be submitted for revision in specifications*
2.	**3.2.P.8**	Results of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted
3.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted **including ADC-attested invoice/clearance certificate.**	*ADC attested invoice / clearance certificate is not submitted.*

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Registration Board further decided that registration letter will be issued after submission of following:

Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.

1064.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals** **3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000667 renewed w.e.f. from 10-06-2019 and approval letter for the following four sections: Tablet (General), Capsule (General), Dry Powder for Sachet (General) & Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30472 dated: 27-10-2022
	Details of fee submitted	PKR 30,000/- DS No. 714112214231
	The proposed proprietary name / brand name	**DAPAGLIF 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin (as Propanediol Monohydrate)…..5mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Film coated immediate release tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Farxiga 5mg Tablet by AstraZeneca (USFDA approved).
	For generic drugs (me-too status)	Daploz 5mg Tablet by Highnoon Highnoon Laboratories Ltd. (Reg.No. 098425).
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, Provincial Highway 237, Huaian Economic Development Zone, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and their verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated and real time conditions of Zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 12 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition,

		pharmaceutical development, manufacture, manufacturing process and control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product i.e. Daploz 5mg Tablet by Highnoon Highnoon Laboratories Ltd. Firm has submitted CDP results of their product against the comparator product i.e. Daploz 5mg Tablet by Highnoon Highnoon Laboratories Ltd in three dissolution media (i.e. pH 1.2, pH 4.5, pH 6.8. Dissolution is more than 85% in 15 minutes so calculation for similarity factor is not required.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	7100-202111001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	2500 tablets.	2500 tablets.	2500 tablets.
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	16-06-2022	16-06-2022	16-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS2020921) dated 21-09-2020 issued by Jiangsu Drug Administration. The certificate specifies that the firm complies with Chinese GMP for pharmaceutical products. The certificate is valid till 20-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of 1.5kgs Dapagliflozin Propendiol

		Monohydrate cleared by AD (I&E) DRAP, Lahore dated 07-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
1065	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals** **3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000667 renewed w.e.f. from 10-06-2019 and approval letter for the following four sections: Tablet (General), Capsule (General), Dry Powder for Sachet (General) & Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30475 dated: 27-10-2022
	Details of fee submitted	PKR 30,000/- DS No. 97697883919
	The proposed proprietary name / brand name	**DAPAGLIF 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin (as Propanediol Monohydrate)…..10mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Film coated immediate release tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Farxiga 10mg Tablet by AstraZeneca (USFDA approved).

	For generic drugs (me-too status)	Daploz 10mg Tablet by Highnoon Highnoon Laboratories Ltd. (Reg.No. 098426).
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, Provincial Highway 237, Huaian Economic Development Zone, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and their verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated and real time conditions of Zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 12 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product i.e. Daploz 10mg Tablet by Highnoon Highnoon Laboratories Ltd. Firm has submitted CDP results of their product against the comparator product i.e. Daploz 10mg Tablet by Highnoon Highnoon Laboratories Ltd in three dissolution media (i.e. pH 1.2, pH 4.5, pH 6.8. Dissolution is more than 85% in 15 minutes so calculation for similarity factor is not required.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. No. 18, 237 Provincial	

	Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	7100-202111001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	2000 tablets.	2000 tablets.	2000 tablets.
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	16-06-2022	16-06-2022	16-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS2020921) dated 21-09-2020 issued by Jiangsu Drug Administration. The certificate specifies that the firm complies with Chinese GMP for pharmaceutical products. The certificate is valid till 20-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of 1.5kgs Dapagliflozin Propendiol Monohydrate cleared by AD (I&E) DRAP, Lahore dated 07-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1066.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth Pharma (Pvt) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**

	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27914: 03-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 778441198
	The proposed proprietary name / brand name	OTOMYCIN-D Ear drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Tobramycin…3mg Dexamethasone…1mg
	Pharmacotherapeutic Group of (API)	Corticosteroids, moderately potent, combinations with antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	5ml
	The status in reference regulatory authorities	Not submitted for ear drops
	For generic drugs (me-too status)	Arodex ear drops (Reg. No. 78661) of M/s Jaens Pharmaceutical Industries Pvt Ltd

Evaluation by PEC (No XXIII):

Sections	Observations/Deficiencies/ Short-comings
--------	The reference product is eye drops instead of ear drops. Moreover, finished product specifications are given as USP whereas in USP, ophthalmic suspension preparation monograph is available instead of otic suspension. Justification shall be submitted for the pharmaceutical form of the applied formulation. If the product is otic preparation, prescribed fee shall be submitted for change in specifications from USP to other, as the case may be.
----------	GMP certificate of drug product manufacturer for ear drops (steroidal) section shall be submitted.
3.2.S.4.2	Analytical procedure submitted is just monograph of both APIs and not a step by step procedure used in the lab by the applicant for raw material analysis.
3.2.S.4.3	Raw data and chromatograms of Analytical method verification of both APIs conducted by drug product manufacturer shall be submitted.
3.2.S.5	In-house method of analysis is given. The method of analysis must be validated according to ICH guidelines and report and associated data of validation shall be submitted.
3.2.P.8	Stability studies have not been conducted according to Zone Iva conditions. The complete stability studies report and associated data shall be submitted as per Zone Iva conditions.
3.2.P.8	Approval of API/ DML/GMP certificate of APIs manufacturers issued by concerned regulatory authority of country of origin shall be submitted. Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted including clearance certificates issued by DRAP.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1067.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29851: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 89201210
	The proposed proprietary name / brand name	SINCALCET 30mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……30mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available
1068.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29850: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 45011133195
	The proposed proprietary name / brand name	SINCALCET 60mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……60mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available
1069.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29851: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 4237851354
	The proposed proprietary name / brand name	SINCALCET 90mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……90mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available

Evaluation by PEC (No….):

Sections	Observations/Deficiencies/ Short-comings
----------	Clarify the enantiomer of API.
1.5.2	The reference product contains 30mg, 60mg, 90mg equivalent base of Cinacalcet HCl. The label claim shall be changed according to the reference product along with full fee of registration.
1.5.8	Me-too for Cinacalcet 90mg is not available. It shall be applied as a new drug product and differential fee of Rs. 45000/- shall be submitted.
----------	The yield of stability batches given in BMRs is as low as 48% percent. E.g. 16 packs of 30's were placed for stability studies of Cinacalcet 30mg. Justify. Also justify how this quantity is sufficient to conduct testing of stability batches throughout the proposed shelf life of the drug product.
3.2.S.4.3	Raw data and chromatograms of Analytical method verification of API conducted by drug product manufacturer shall be submitted.
3.2.P.5	The dissolution specifications are given as NLT 70 % after 15 minutes and NLT 80% (Q) after 45minutes. Justification shall be submitted. The method of analysis must be validated according to ICH guidelines and report and *associated data* of validation shall be submitted.
3.2.P.2.2.1	CDP is performed using UV Visible spectrophotometer instead of HPLC. Justify. Provide complete details of the product (including brand name, strength, manufacturer's name) against which pharmaceutical equivalence and CDP is conducted.
3.2.P.8	Material imported against clearance certificate issued by DRAP dated 18-07-18 specifying 2kg API has previously been utilized in stability batches and data of the same was presented in 296th meeting of RB. Complete consumption details of the imported material shall be submitted as it has been used in the manufacturing of current and previous stability batches for all three strengths.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1070.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Plot No. A-56, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Plot No. A-56, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 02/2021-DRAP (K) dated 25-01-2021 based on evaluation conducted on 29-10-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of regularization of building layout plan for various sections including tablet (general) section dated 28-12-2020.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29329 dated 17-10-2022.
	Details of fee submitted	PKR 75,000/- DS No. 571631900
	The proposed proprietary name / brand name	**ERTULIX 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin (as Ertugliflozin L-Pyroglutamic Acid)……15mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Oblong biconvex film coated tablet with score line on one side
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 15mg (MHRA & USFDA Approved)
	For generic drugs (me-too status)	Ertuvia Tablet 15mg of M/s Ferozsons Laboratories Ltd (Reg. No. 110363)
	Name and address of API manufacturer.	Chifeng Arker Pharmaceutical Technology Co. Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time

	studies)	conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro 15mg Tablet by MSD Sub Merck. Firm has submitted CDP results of their product against the innovator's product Steglatro 15mg Tablet in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.		
API Lot No.	D84-210601		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-119	TR-120	TR-121
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	24-12-2021	24-12-2021	24-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 16-08-2021 specifying 735grams of

		Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
1071.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Plot No. A-56, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Plot No. A-56, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 02/2021-DRAP (K) dated 25-01-2021 based on evaluation conducted on 29-10-2020.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29330 dated 17-10-2022.
	Details of fee submitted	PKR 75,000/- DS No. 40068456
	The proposed proprietary name / brand name	ERTULIX 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin (as Ertugliflozin L-Pyroglutamic Acid)……5mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Oblong biconvex film coated tablet with score line on one side
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 14's, 20's, 28's &30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 5mg (MHRA & USFDA Approved)

	For generic drugs (me-too status)	Ertuvia Tablet 15mg of M/s Ferozsons Laboratories Ltd (Reg. No. 110362)
	Name and address of API manufacturer.	Chifeng Arker Pharmaceutical Technology Co. Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro 5mg Tablet MSD Sub Merck. Firm has submitted CDP results of their product against the innovator's product Steglatro 5mg

		Tablet in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.		
API Lot No.	D84-210601		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-122	TR-123	TR-124
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	24-12-2021	24-12-2021	24-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 16-08-2021 specifying 735grams of Ertugliflozin L-Pyroglutamic Acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
1.	**1.3.5**	Firm has submitted copy of approval letter of regularization of building layout plan for various sections including tablet (general) section dated 28-12-2020. Approval letter of the	Applicant has submitted report of inspection for DML renewal conducted on 29-10-2020.

		tablet (general) section needs to be submitted or panel inspection report conducted for renewal of DML or grant of GMP certificate.	
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Submitted on the basis of inspection conducted on 01-08-2023 specifying Tablet (general) section.
3.	**3.2.S.4.4**	Batch analysis report of the relevant batch of API used in stability studies shall be submitted from drug substance and drug product manufacturer.	Submitted.
4.	**3.2.P.5**	As the applied specifications are Manufacturer's Specifications, the applicant shall submit analytical method validation studies according to ICH Q2 guidelines.	Submitted.
3.	**3.2.P.8**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
4.		Provide complete consumption record of the imported raw material as the material is used in a range of trial products.	Submitted.
5.		Executed BMRs and stability data sheets of 15mg strength shall be submitted	Submitted.

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1072.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 968: 11-01-2023
	Details of fee submitted	PKR 75,000/- : DS No. 9624721088
	The proposed proprietary name / brand name	**AMPRID INJCETION 5mg/2mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2mL vial Contains: Amisulpride……..5mg
	Pharmacotherapeutic Group of (API)	Antipsychotics; Benzamides
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	2ml vial
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	New drug

Evaluation by PEC (No…XXIII):

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
	1.3.5	Evidence of availability of SVP section and its approval from DRAP shall be submitted.	Firm has submitted Letter No. F.2-12/93-Lic (Vol-V) dated 20-09-2021 for DML renewal wef 22-09-2020 specifying Liquid injection (Ampule, vial, infusion) (General) section. Firm has also submitted that a number of SVP and LVP products have been registered in its name.
	------	Valid GMP certificate of the drug product manufacturer shall be submitted.	GMP certificate issued on the basis of evaluation conducted on 06-06-2023 is submitted specifying Liquid injection (Ampule, vial, infusion) (General) section.
	3.2.R.1	The innovator's product literature states that the product is subject to photodegradation. What steps were taken during manufacturing and testing of drug product to prevent/minimize photodegradation.	The innovator product literature showed "Protect from light BARHEMSYS is subject to photodegradation," therefore Manufacturing and Testing Operations were carried out at light with low lux level along with strict temperature and humidity control to maintain the integrity of the subjected product.
	3.2.S.4.3	Analytical method verification of drug substance by drug product manufacturer shall be submitted.	Submitted.
	3.2.P.8	Documents for the procurement of API with approval from DRAP shall be submitted and approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of commercial invoice cleared on 17-02-2021 specifying import of 5kg of Amisulpride. The invoice is cleared by AD (I&E) DRAP, Karachi. Applicant has also submitted Form 6 and GMP certificate of API manufacturer i.e. M/s Sun Pharmaceuticals Industries Ltd, Madhya Pradesh, India.
	3.2.P.8	Gap between the initiation of stability studies and manufacturing of stability batches is two months. Justify.	Justified according to the stability study protocol of the applicant.

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1073.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**

	Name, address of Manufacturing site.	M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2737 : 31-01-2023
	Details of fee submitted	PKR 75,000/- : DS No. 04587008161
	The proposed proprietary name / brand name	**Dapwiz Plus XR 2.5/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated bilayered Tablet Contains: Dapagliflozin as Propanediol Monohydrate…2.5mg Metformin Hcl as Extended Release…1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)
	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No. 105283)

Evaluation by PEC (No.XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings	Response of applicant
1.	3.2.S.4.3	Analytical method verification of Dapagliflozin conducted by drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.4	Lot No. of APIs used in stability batches shall be clarified and batch analysis results shall be submitted accordingly.	Submitted.
3.		Executed BMRs of stability batches shall be submitted	Submitted.

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1074.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2103: 23-01-2023
	Details of fee submitted	PKR 30,000/- : DS No.: 652192266025
	The proposed proprietary name / brand name	**NEWS-GOR Syrup 0.25mg/5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Syrup Contains: Pizotifen (as Hydrogen Malate)…0.25mg
	Pharmacotherapeutic Group of (API)	Analgesics (Anti migraine)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	60ml, 90ml, 120ml
	The status in reference regulatory authorities	Sanomigran Elixir (MHRA Approved)
	For generic drugs (me-too status)	Pizosrch 0.25mg/5ml Syrup of M/s Medisearch Pharmacal (Pvt) Ltd (Reg. No. 113334)

Evaluation by PEC (No.XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.		DML of applicant was issued/renewed on 18-02-2018. DML renewal due in 2023 shall be submitted.
2.	3.2.P.1	The reference product is an *elixir* with the following excipients: Raspberry flavour 50969, maraschino flavour, methyl hydroxybenzoate, propyl hydroxybenzoate, citric acid (anhydrous), disodium phosphate (anhydrous), maltitol liquid, ethanol 96% and purified water. However, the master formulation of applied product contains the following excipients and applicant has claimed that it is a syrup: Sorbitol solution at 70 % (non-crystallizing), Glycerol, Propylene glycol (PG), Saccharin sodium, Methyl Paraben sodium, Propyl Paraben sodium, Chocolate Liquid flavor, Sodium Citrate and Purified water. i. Justify the use of qualitatively different excipients than the reference product and submit excipient compatibility studies. ii. Also clarify whether the applied and reference products are syrups or elixirs with clear scientific rationale. iii. Composition of the Drug Product includes Glycerine/Glycerol, Sorbitol and Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the three excipients: • Vendor name, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.
3.	3.2.R.1 & 3.2.P.1	Submit data in section 3.2.P.1 and BMRs as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated

		(e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".
4.	3.2.P.5.3	Analytical Method Validation report of drug product with results and associated data of "Robustness" shall be submitted.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1075.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nicholas Pharmaceuticals. Plot No. 34, St. No. SS-02, National Industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals. Plot No. 34, St. No. SS-02, National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No.1828: 19-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit Slip No.50487151953
	The proposed proprietary name / brand name	**NOOPEM 2gm Powder for Solution for infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem as Trihydrate……2gm (Blended with sodium bicarbonate)
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	New drug. Me-too is not available.

Evaluation by PEC (No…XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.	1.5.8	Submit differential fee since the applied formulation is not yet registered in Pakistan. Me-too is not available
2.		Valid GMP certificate of the applicant shall be submitted.
3.	2.3.R.1.1	Justify the supply of 2g finished product in 20mL glass vial as the required concentration is 50mg/ml for IV infusion and 1mg/ml to 20mg/ml for IV injection, according to reference product literature. Also submit factor
4.	3.2.S.4.1	CoA of drug substance states that the material conforms to USP specifications. Specifications of drug substance in 3.2.S.4.1 shall be submitted according to USP along with requisite fee.
5.	3.2.S.4.4	CoA by drug product manufacturer does not include test for sodium content. Complete CoA with test results of all tests given in USP/ CoA of drug substance manufacturer, shall be submitted.
6.	3.2.P.1	Submit data in section 3.2.P.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated

		(e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".
7.	3.2.P.2.2.1	Pharmaceutical equivalence is conducted against Meronem 1g injection of M/s Pfizer Pakistan Ltd, Karachi. The reference product differs in terms of fill weight. Justification shall be submitted in this regard.
8.	3.2.P.2.6	Compatibility studies shall be submitted for drug product with 0.9% NaCl solution and 5% dextrose solution which are the diluents to be used for solution for **infusion**, according to the reference product literature.
9.	3.2.P.5.2	Atomic absorption spectroscope with sodium hollow cathode lamp is required for testing content for sodium. Evidence of availability of the required instruments shall be submitted.
10.	3.2.P.8	Valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
11.	3.2.P.8	Firm shall submit certificate of 21 CFR compliance and audit trail reports for the HPLC system used in analysis.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1076.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi**
	Name, address of Manufacturing site.	M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36122: 12-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit Slip No.:16452579167
	The proposed proprietary name / brand name	**DEXA 0.1% eye drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Dexamethasone……1mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory Agents, Corticosteroids, plain
	Reference to Finished product specifications	Not submitted
	Proposed Pack size	1 x 5ml
	The status in reference regulatory authorities	Maxidex eye drops (MHRA approved)
	For generic drugs (me-too status)	Not submitted

Evaluation by PEC (No…XXIII):

Sr. No.	**Module/Section**	**Observations/Deficiencies/ Short-comings**
	Module 2 & 3	Submit complete, properly arranged, organized and tagged dossier according to "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use."

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1077.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31343: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 0758230142
	The proposed proprietary name / brand name	**DAPIL 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate 6.35mg equivalent to Dapagliflozin……5 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	14's
	The status in reference regulatory authorities	Farxiga 5mg & 10mg (USFDA Approved)
	For generic drugs (me-too status)	Dapa Tablet 5mg & 10mg of M/s Hilton
1078.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31342 : 02-11-2022
	Details of fee submitted	PKR 30,000/- : 76702314
	The proposed proprietary name / brand name	**DAPIL 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate 12.7mg equivalent to Dapagliflozin……10 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	14's

	The status in reference regulatory authorities	Farxiga 5mg & 10mg (USFDA Approved)
	For generic drugs (me-too status)	Dapa Tablet 5mg & 10mg of M/s Hilton

Evaluation by PEC (No… XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.7	Shelf life assigned to drug substance is 36 months. Stability studies data of drug substance is submitted for 24 months. Long term/ Real time stability studies data shall be submitted as per zone Iva conditions *for complete shelf life of the drug substance*
2.	1.6.5 & 3.2.S.2.1	Drug Import License is submitted. Address on DIL is same as GMP certificate. However, on the NMPA website, the name of manufacturer against the GMP number is different from that on the hard copy submitted by the applicant. Moreover, address of manufacturing site on the submitted DML is different from that given on the GMP certificate.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1079.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Relizon Pharmaceuticals. Plot No. 118 Sunder Industrial Area, Lahore.**
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals. Plot No. 118 Sunder Industrial Area, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32003: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 871610912313
	The proposed proprietary name / brand name	**MEBENZONE 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable coated tablet contains: Mebendazole ……100 mg
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1’s, 10’s, 30’s, 60’s, 100’s, 300’s
	The status in reference regulatory authorities	Vermox 100mg chewable tablet (MHRA Approved)
	For generic drugs (me-too status)	Mebzole 100mg Tablet by M/s Bio Labs (Reg. no. 112930)
1080.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Relizon Pharmaceuticals. Plot No. 118 Sunder Industrial Area, Lahore.**
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals. Plot No. 118 Sunder Industrial Area, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32002: 07-11-2022
	Details of fee submitted	PKR 30,000/- : DS No……..
	The proposed proprietary name / brand name	**MEBENZONE 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable coated tablet contains: Mebendazole ……500 mg
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's, 10's, 30's, 60's, 100's, 300's
	The status in reference regulatory authorities	Vermox 500mg chewable tablet (USFDA Approved)
	For generic drugs (me-too status)	Wosan 500mg Tablet by M/s Glitz Pharma (Reg. No. 104933)

Evaluation by PEC (No.XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.	1.3.5	Renewal of DML No. 000875 due in 02-2023 issued by Licensing Division of DRAP shall be submitted.
2.	2.3.R.1.1 & 3.2.S.1	Mebendazole drug substance exhibits polymorphism. Clarify the polymorph used in the formulation and provide scientific justification and rationale for use of that specific polymorph.
3.	3.2.S.4.3	Analytical Method Verification studies for drug substance including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.
4.	3.2.P.1 & 3.2.P.3.2	In Product master formula, the given quantity of API per tablet is 105mg for 100mg strength tablet. Justify the use of overages in the formulation.
5.	3.2.P.1	Test results for residual solvents shall be submitted as the reference product contains 2-propanol.
6.	3.2.P.2.2.1	Pharmaceutical equivalence and CDP has been performed with Vermox tablets. Submit details of the reference product including its manufacturer's name, manufacturing site, batch number, manufacturing and expiry date.
7.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin and *DRAP attested invoice* shall be submitted.
8.	3.2.P.8	Certificate of 21 CFR compliance for the HPLC system used for drug substance and drug product testing shall be submitted.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1081.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals** **3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32814 : 15-11-2022
	Details of fee submitted	PKR 30,000/- : 4998401625
	The proposed proprietary name / brand name	**FEMECARE Cream 1% w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Clotrimazole……10mg
	Pharmacotherapeutic Group of (API)	Antifungal for topical use
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10g, 15g, 30g
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Canesten Clotrimazole Cream (Reg no. 107227) by M/s Bayer
Evaluation by PEC (No…XXIII):		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1082.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals** **3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5680 : 28-02-2023
	Details of fee submitted	PKR 30,000/- : 335142119354
	The proposed proprietary name / brand name	**FEMECARE-B Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Clotrimazole…10mg Betamethasone as Dipropionate…0.5mg
	Pharmacotherapeutic Group of (API)	Corticosteroids combinations with antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10g, 15g, 30g
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Seket cream (Reg no. 111996) by M/s Seraph Pharmaceutical

Evaluation by PEC (No…XXIII):

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation as per the commitment submitted in the registration application.

1083.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5490 : 27-02-2023
	Details of fee submitted	PKR 30,000/- : 98906195864
	The proposed proprietary name / brand name	DAPXI-MET XR Tablet 5mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……5 mg (immediate release) Metformin HCl (as extended release)…….1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)
	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No.)

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.S.2.1 & 3.2.P.8	Valid approval of API/ DML/GMP certificate of Metformin API issued by concerned regulatory authority of country of origin shall be submitted.	GMP certificate valid till 20-06-2026 is submitted.
2.	3.2.P.5.1	Release specifications of innovator include testing for total microbial count and testing for E.coli whereas specifications given in 3.2.P.5.1 do not include these two tests. Submit revised product specifications along with the prescribed fee.	Submitted.
3.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.
4.	3.2.R.1	Filled BMRs of stability batches shall be submitted.	Submitted.

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.
Registration Board further decided that registration letter will be issued after submission of following:
Fee of PKR7500/- for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.

1084.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37707: 26-12-2022
	Details of fee submitted	PKR 30,000/- : 816783029
	The proposed proprietary name / brand name	**WOLIDE 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……400 mg
	Pharmacotherapeutic Group of (API)	Antiinfectives For Systemic Use
	Reference to Finished product specifications	Innnovator's Specifications
	Proposed Pack size	12's
	The status in reference regulatory authorities	Zyvox Tablet (USFDA Approved)
	For generic drugs (me-too status)	Ecasil Tablet by M/s Sami (Reg. No. 67162)

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.S.1.2	Applicant has stated that API manufacturer is manufacturing polymorphic Form II. As the drug substance exhibits polymorphism, justification for the use of polymorphic Form II shall be submitted along with credible evidence.
2.	3.2.S.4.2, 3.2.S.4.3 & 3.2.S.4.4	Analytical procedure is not as per USP monograph. API conforms to USP as per CoA in 3.2.S.4.4. Clarify and submit analytical method and analytical method verification, accordingly
3.	3.2.P.5.2 & 3.2.P.5.3	In method of analysis of Linezolid tablets, the chromatographic conditions for dissolution and Assay testing are as follows: Lambda 254nm Flow rate: 1.5ml/min Column: L1 Injection: 10micro L However, the above conditions are not as per USP monograph. Justify.

		Moreover, validation/verification studies have been submitted for the method given in 3.2.P.5.2 while the method is not as per USP. Justify.
4.	3.2.P.8	Tests results and associated testing record of stability batches shall be submitted for real time and accelerated stability studies *at the six-point time point.* (12-2022)
5.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. Documents for the procurement of API with approval from DRAP shall be submitted as the already submitted invoice is not attested by ADC, DRAP.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

1085.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31429: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 313632096867
	The proposed proprietary name / brand name	**ACETAM 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Piracetam …….…400 mg
	Pharmacotherapeutic Group of (API)	Nootropic (Psycholeptics) WHO ATC code: N06BX03
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3 x 10's
	The status in reference regulatory authorities	Piracetam Biogaran 400 and 800 mg film coated tablet (ANSM Approved)
	For generic drugs (me-too status)	Actopil 400mg Tablet by M/s Wimits Pharmceuticals (reg. No. 99709)
1086.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt) Ltd 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31430: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 40845250
	The proposed proprietary name / brand name	**ACETAM 800mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Piracetam ……..…800 mg
	Pharmacotherapeutic Group of (API)	Nootropic (Psycholeptics) WHO ATC code: N06BX03
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3 x 10's
	The status in reference regulatory authorities	Piracetam Biogaran 400 and 800 mg film coated tablet (ANSM Approved)
	For generic drugs (me-too status)	Pirajen 800mg Tablet by M/s Jenner (reg. No. 108164)

Evaluation by PEC (No….):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	1.3.4	Drug Manufacturing License (DML) renewal was due in 12-2019. Copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP shall be submitted.	Copy of DML renewed wef 24-12-2019 is submitted.
2.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued *within the last three years* shall be submitted.	GMP certificate based upon evaluation conducted on 13-10-2023 & 07-1-2023 is submitted specifying Tablet (general) section.

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

b. Deferred cases

1087.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Dahgal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 04-11-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of revised section dated 27-02-2023 specifying Soft Gelatin Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No HQH-8E1-ELN7 dated 22-02-2024
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 1091814695
	The proposed proprietary name / brand name	**Isotin 40mg Soft gelatin capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Isotretinoin……40mg
	Pharmacotherapeutic Group of (API)	Anti-acne preparations for systemic use, Retinoids for treatment of acne
	Pharmaceutical form of applied drug	Oral soft gel capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA & MHRA Approved
	For generic drugs (me-too status)	Maxinoin Capsule 40mg of M/s Maxitech Pharma (Pvt) Ltd (Registration No.108920)
	Name and address of API manufacturer.	M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore – 452015(India).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ±

		5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and Comparative Dissoultion Profile of their product against the comparator product Maxinoin 40mg Soft gel capsules of M/s Maxitech Pharma (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore –452015(India).		
API Lot No.	HBPL/ISO/22-23/007		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 1, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	073NS01	073NS02	073NS03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	20-04-2023	20-04-2023	20-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted for relevant unit of API manufacturer.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 05-04-2023 specifying 1kg of Isotretinoin. The certificate is issued by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**2.3.S.4.4 & 3.2.S.4.4**	CoAs of three batches of API are submitted i.e. 2009065, IST-20230706 (generated by Chongqing Huapont Pharm. Co. Ltd) and HBPL/ISO/22-23/007 (generated by Horster Biotek). Clarification shall be submitted regarding the manufacturer of drug substance along with submission of following: • CoA (from manufacturer and applicant) of the batch of drug substance used in the manufacturing of stability batches. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Batch No. of API used in the manufacturing of stability batches is HBPL/ISO/22-23/007 manufcatured by M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore – 452015(India). CoAs (from manufacturer and applicant) are subnmitted. Approval of API/ DML/GMP certificate of *relevant site* of API manufacturer issued by concerned regulatory authority of country of origin.
2.	**3.2.P.8**	Results and raw data of real time and accelerated stability studies of FPP shall be submitted for 6 month time point	Submitted.
3.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Submitted.

Decision of 335th meeting of RB: Deferred for submission of valid DML/GMP certificate of drug substance manufacturer issued by the relevant authority of country of origin.

Reply of applicant: Applicant has submitted copy of DML retention certificate of M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore – 452015(India) valid till 20-11-2027 issued by the relevant authority of country of origin..

Remarks of Evaluator[xxiii]:

Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1088.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fassgen Pharmaceuticals Plot # 67/1 Block-A Phase III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals Pvt Ltd, 30km Lahore Sargodha Road, Sargodha.
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 10-04-2022 is provided)
	GMP status of the firm	GMP certificate of the contract acceptor is not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-02-2018 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 32010 dated 07-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip No. 7727370183
	The proposed proprietary name / brand name	**VENSET 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syrup contains: Ondensetron Hydrochloride equivalent to Ondensetron …… ……4mg
	Pharmacotherapeutic Group of (API)	Anti-emetics and Anti-nauseants
	Pharmaceutical form of applied drug	Transparent Syrup
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml & 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondensetron Syrup (MHRA Approved)
	For generic drugs (me-too status)	Dantron Oral Solution of M/s Shrooq Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 77076)
	Name and address of API manufacturer.	Aungraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Onseron Syrup. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Anugraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, India.		
API Lot No.	AR/078/19 in Batch No.s 003 & 004. AR/149/20 in Batch No. 005		
Description of Pack (Container closure system)	Amber coloured glass bottle with aluminium cap		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	003	004	005
Batch Size	10000 packs	10000 packs	10000 packs
Manufacturing Date	11-2020	03-2021	05-2021
Date of Initiation	17-11-2020	11-03-2021	28-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. DCD/SPL.CI-I/CR-1884/18-19 dated 16-02-2019 issued by Drugs Control Department, Government of Karnataka. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. The certificate was valid for one year from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.
6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.
9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.

11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.
14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.

Decision of 331st meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of applicant:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.	Receiving of DML renewal application submitted in Licensing Division of DRAP dated 06-02-2023 is submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.	GMP certificate No. 248/2022-DRAP (AD-0835218-1099) issued on the basis of evaluation conducted on 25-11-2022 is submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.	Submitted
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.	Submitted
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.	Applicant has submitted complete calculations including adjustment of salt factor. Applicant has also clarified that the fill weight is 50mL in 60mL bottle. API quantity is not changed. The applied label claim is correct.
6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.	Submitted
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.	M/s Indus Pharma Pvt Ltd, Karachi. Reg. No. 058677
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.	Submitted

9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.	*PL/ Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product.*
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.	CoA of glycerine Batch No. 0800, Mfg dtae 23-09-2022, Expiry 24-09-2024 from vendor (OleoCorp) is submitted. This batch was manufactured after the manufacturing of stability batches. CoA/test report generated by manufacturer is also not submitted. ***Reply is not satisfactory***
11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.	Submitted
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	GMP certificate dated 10/04/2023 and valid till one year from the date of issue is submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.	Firm has submitted clearance certificate dated 22-10-2020 specifying import of 5kg Ondensetron HCl by M/s Winlet. The clearance certificate is issued by AD (I&E) DRAP, Lahore. Batch No. of imported batch is AOND-20013, Mfg 09-2020, Exp 08-2025. Batch No. of API used for manufacturing of stability batches is different. ***Clarification shall be submitted by the applicant.***
14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.	Submitted
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.	Submitted

Remarks of Evaluator[xxiii]: Response of applicant is not satisfactory.

Decision: Registration Board decided to defer the application for the following reasons:

i. **Submission of CoA/test report of relevant batch of Glycerin generated by manufacturer,**
ii. **Clarification regarding the batch of glycerin used in the manufacturing of stability batches,**
iii. **Clarification regarding the batch of API used in the manufacturing of stability batches,**
iv. **Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product. If excipients of applied formulation are different from reference product, drug-excipient compatibility studies shall also be submitted.**

1089.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22609 dated 14-09-2023
	Details of fee submitted	PKR 30,000/- Dated 24-03-2023
	The proposed proprietary name / brand name	**F-ZOLE 150mg Capsule** **FLUZONE 150mg Capsule** **FLU-GM 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole……150mg
	Pharmacotherapeutic Group of (API)	Antimycotics For Systemic Use
	Pharmaceutical form of applied drug	Hard gelatin capsule filled with white to off white powder
	Reference to Finished product specifications	BP
	Proposed Pack size	1's, 4's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azocan 150mg capsule (MHRA Approved)
	For generic drugs (me-too status)	Fantizol Capsule of M/s Apex Pharmaceuticals (Pvt) Ltd, Karachi (Reg.No. 073551)
	Name and address of API manufacturer.	Horster Biotek Pvt, Ltd. Khasra No. 259, Plot No. 1&2, Gram Sukhlia, Sanwer Road, Industrial Area, Indore M.P, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Diflucan Capsule 150mg manufactured by M/s Pfizer Pakistan Ltd. Firm has submitted CDP results of their product against the innovator's product Diflucan Capsule 150mg in three dissolution media. The similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Horster Biotek Pvt, Ltd. Khasra No. 259, Plot No. 1&2, Gram Sukhlia, Sanwer Road, Industrial Area, Indore M.P, India.
API Lot No.	HBPL/FCZ/20-21/010

Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRC-016	TRC-017	TRC-018
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	03-12-2021	03-12-2021	03-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. INDBGMP202211255) dated 30-11-2022 issued by Food and Drugs Control Administration Madhya Pradesh, India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Fahmir Pharma Pvt Ltd, Lahore dated 29-11-2021 specifying 1Kg loan of Fluconazole. Firm has also submitted clearance certificate dated 19-11-2020 specifying import of 25kg Fluconazole. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.S.5 & 3.2.P.6**	The submitted CoA of reference standard in 3.2.S.5 is not legible. CoA of reference standard including source and lot number shall be submitted.	CoA of Fluconazole USP raw material is submitted *whereas COA of reference standard is required.*
2.	**2.3.R.1.1**	Provide copies of filled BMRs of all three stability batches of drug product.	Submitted.

Decision of 333rd meeting of RB: Deferred for submission of CoA of reference/working standard used for analysis of stability batches along with details of source/grade and lot number of primary reference standard against which it was standardized.

Sr. No.	Sections	Reason of deferment	Reply of applicant
1	**3.2.S.5 & 3.2.P.6**	Deferred for submission of CoA of reference/working standard used for analysis of stability batches along with details of source/grade and lot number of primary reference standard against which it was standardized.	Applicant has submitted CoA of working standard of Fluconazole (USP) of Batch No. HBPL/FCZ/20-21/001/WS, Mfg date 10/10/2020, Expiry date 09/10/2024 by M/s Horster Boitek Pvt Ltd, India.

Remarks of Evaluator[xxiii]:. Details of source/grade and lot number of primary reference standard against which the working standard was standardized shall be submitted.

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Registration Board further decided that registration letter will be issued after submission of following:

Details of source/grade and lot number of primary reference standard against which the working standard was standardized.

Case no. 03 Registration applications of newly granted DML or New section (Human)

a. New /Additional section(s)

Ref. Letter No.F.1-18/92-Lic (Vol-III) dated 27-02-2023, the CLB in its 289th meeting approved section Soft Gel Capsules (General)-New to M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi. (DML No.000333)

1090.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking No. LWR-HEZ-47VR: 31-01-2024
	Details of fee submitted	PKR 30,000/- : DS No. 68270874016

	The proposed proprietary name / brand name	ISOTIN 20mg soft gelatin capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Isotretinoin……20mg
	Pharmacotherapeutic Group of (API)	Anti-acne preparations for systemic use, Retinoids for treatment of acne
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	3 x 10's
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Maxinoin Capsule 20mg of M/s Maxitech Pharma (Pvt) Ltd (Registration No.82177)
Evaluation by PEC (No.XXIII):		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1091.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking No. 8BB-8WM-1QM8: 23-11-2023
	Details of fee submitted	PKR 30,000/- : DS No. **81913667800**
	The proposed proprietary name / brand name	ISOTIN 10mg soft gelatin capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Isotretinoin……20mg
	Pharmacotherapeutic Group of (API)	Anti-acne preparations for systemic use, Retinoids for treatment of acne
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	3 x 10's
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Maxinoin Capsule 20mg of M/s Maxitech Pharma (Pvt) Ltd (Registration No.82176)
Evaluation by PEC (No…XXIII):		
Decision: Approved.		

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Ref. Letter No.F.1-12/89-Lic (Vol-IV) dated 27-09-2021, the CLB in its 282nd meeting approved grant of additional section Lotion (General) to M/s Bio-Labs (Pvt) Ltd, Plot 145, Industrial Triangle, Kahuta Road, Islamabad. (DML No.000296)

1092.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. Q8L-9QJ-BSAU : 21-02-2024
	Details of fee submitted	PKR 30,000/- DS No. 7277251828
	The proposed proprietary name / brand name	KT-Zole Lotion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Ketoconazole……20mg
	Pharmacotherapeutic Group of (API)	Antifungals For Topical Use
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	30 ml ,60ml, 100ml & 120ml
	The status in reference regulatory authorities	Nizoral Shampoo; MHRA approved
	For generic drugs (me-too status)	Ketowin Lotion by M/s Shaigan

Evaluation by PEC [(xxiii)] :

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
1.		Applied dosage form is lotion whereas reference product is a shampoo. Excipients of applied product are qualitatively the same as reference product. Clarify the dosage form.	Medicated shampoo based scalp lotion
2.	**1.5.2** **3.2.P.1**	Label claim of reference product is Ketoconazole 2% w/w whereas applicant has submitted label claim as w/v. Clarify.	Label claim revised.
3.		Executed BMRs of stability batches shall be submitted.	Submitted
4.	**3.2.P.8**	Documents for procurement of API shall be submitted along with approval of API from relevant country of origin	Submitted
5.	**3.2.P.8**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions for 6 month time point.	Submitted

Decision: Approved with following label claim:
"Each gram contains:
Ketoconazole……20mg"

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1093.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. THN-M1A-Y7WA: 19-03-2024
	Details of fee submitted	PKR 30,000/- DS No. 494423944
	The proposed proprietary name / brand name	Hydrosone 2.5% Lotion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Hydrocortisone……25mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml, 60ml, 120ml
	The status in reference regulatory authorities	Could not be verified
	For generic drugs (me-too status)	Lacticare HC 2.5% Lotion by M/s GSK (Reg. No. 019739)

Evaluation by PEC [(xxiii)] :

Sr. No.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.9**	Submit evidence of approval of applied formulation in reference regulatory authority as the formulation has been discontinued in USFDA.
2.	**---------**	As the applied product is a steroidal preparation, evidence of separate dispensing facility verified by DRAP shall be submitted along with GMP certificate of the relevant section.
3.	**3.2.P.5.1**	Hydrocortisone acetate lotion monograph is available in USP whereas the applied formulation contains Hydrocortisone. How have you assigned USP specifications to the finished product? Justify with evidence.
4.	**3.2.P.8**	Documents for procurement of API shall be submitted along with approval of API from relevant country of origin
5.	**3.2.P.8**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions for 6 month time point.

Decision: Deferred for submission of satisfactory response to above-cited shortcomings.

Case no. 04 Registration applications of drugs for which stability study data is submitted

a. New cases/ Verification of stability study data/ Exemption from onsite verification of stability data

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that M/s Tabros Pharma Pvt Ltd, Karachi has achieved benchmark of USD 100,000 during fiscal year 2021-2022 and requested for priority consideration of following molecule(s):

1094.	**Name and address of manufacturer / Applicant**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Zontiv-CD 40/12.5mg Tablet
	Composition	Each film coated tablet contains: Azilsartan medoxomil potassium equivalent to Azilsartan Medoxomil……40mg Chlorthalidone.....12.5mg
	Diary No. Date of R& I & fee	Dy.No.378 dated 29-12-2014 (Duplicate dossier), Rs.20,000/- Deposit Slip No.0143752 (Copy), Rs.30,000/- Deposit Slip No. 0275691 (Copy).
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	14's, As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	Edarbylcor Tablet (USFDA Approved)
	Me-too status	Not available
	GMP status	Copy of report of GMP inspection conducted on 05/12/2016 concludes that overall GMP compliance level was good.

STABILITY STUDY DATA

Manufacturer of API	Azilsartan Medoxomil Potassium: M/s CTX Lifesciences Pvt Ltd. Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277/P, 278/P, 279 to 282, 283/P, 284/P GIDC, Sachin, Surat, Gujarat, issued by Food and Drug Administration Gujarat, India. Chlorthalidone: M/s IPQA Laboratories Limited, PO Sejavta, Ratlam, Madhya Pradesh, India.		
API Lot No.	Azilsartan Medoxomil Potassium : 20AK00007 Chlorthalidone: 20003CT6RII		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	TR001-1/ZON-CD	TR002-1/ZON-CD	TR003-1/ ZON-CD
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	23-12-2021	23-12-2021	23-12-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 23118 Dated 16-08-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status

15.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product BAXIB (Apixaban) 2.5mg and 5mg Tablets which was conducted on 05th January, 2021 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available • The firm possesses stability chambers with adequate monitoring and control.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Azilsartan Medoxomil Potassium : Copy of CoA of Batch No. 20AK00007 from M/s CTX Lifesciences (Pvt) Ltd, India is submitted. Copy of CoA of Batch No. 20AK00007 from M/s Tabros Pharma (Pvt) Ltd is submitted. Chlorthalidone: Copy of CoA of Batch No. 20003CT6RII from M/s IPCA Laboratories Ltd, India is submitted. Copy of CoA of Batch No. 20003CT6RII from M/s Tabros Pharma (Pvt) Ltd is submitted.
17.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
18.	Stability study data of API from API manufacturer	Azilsartan Medoxomil Potassium: The firm has submitted copy of **accelerated, 06 Months** (25°C ± 2°C & 60±5%RH) & **long term, 48 Months** (5°C ± 3°C) stability study reports of 03 batches. Chlorthalidone: The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 65±5%RH) & **long term, 60 Months** (40°C ± 2°C, 75±5%RH) stability study reports of 03 batches.
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Azilsartan Medoxomil Potassium: Copy of GMP Certificate No. 22063346 for M/s CTX Lifesciences Pvt Ltd. Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277/P, 278/P, 279 to 282, 283/P, 284/P GIDC, Sachin, Surat, Gujarat, issued by Food and Drug Administration Gujarat, India, valid till 29-05-2025 is submitted. Chlorthalidone: Copy of GMP Certificate No. V/25&28/I.C./I-53/2022/49 for M/s IPQA Laboratories Limited, PO Sejavta, Ratlam, Madhya Pradesh, issued by Food and Drug Administration Madhya Pradesh valid till 31-12-2026 is submitted.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	Azilsartan Medoxomil Potassium: Copy of Form-6, Form 7, Copy of Commercial Invoice No. EI/3002100489 dated 13-01-2020 cleared by ADC (Karachi) dated 25-11-2020 are submitted. Chlorthalidone: Copy of Form-6, Form 7, Copy of Commercial Invoice No. MEG2021/1633335 dated 24-02-2021 cleared by ADC (Karachi) dated 15-03-2021 are submitted.
21.	Protocols followed for conduction of stability study	Submitted
22.	Method used for analysis of FPP	Submitted

23.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
24.	Complete batch manufacturing record of three stability batches.	Submitted
25.	Record of comparative dissolution data (where applicable)	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbyclor Tablet of M/s Takeda Pharmaceutical Company Limited. Firm has submitted CDP results of their product against the innovator's product Edarbyclor Tablet in 3 dissolution medi. The value for similarity factor is in the acceptable range.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

1095.	**Name and address of manufacturer / Applicant**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Zontiv-CD 40/25mg Tablet
	Composition	Each film coated tablet contains: Azilsartan medoxomil potassium equivalent to Azilsartan Medoxomil……40mg Chlorthalidone.....25mg
	Diary No. Date of R& I & fee	Dy.No.8518 dated 12-07-2017 (Duplicate dossier), Rs.20,000/- Deposit Slip No.0143750 (Copy), Rs.30,000/- Deposit Slip No. 0275690 (Copy).
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	14's, As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	Edarbylcor Tablet (USFDA Approved)
	Me-too status	Not available
	GMP status	Copy of report of GMP inspection conducted on 05/12/2016 concludes that overall GMP compliance level was good.

STABILITY STUDY DATA	
Manufacturer of API	Azilsartan Medoxomil Potassium: M/s CTX Lifesciences Pvt Ltd. Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277/P, 278/P, 279 to 282, 283/P, 284/P GIDC, Sachin, Surat, Gujarat, issued by Food and Drug Administration Gujarat, India. Chlorthalidone: M/s IPQA Laboratories Limited, PO Sejavta, Ratlam, Madhya Pradesh, India.

API Lot No.	Azilsartan Medoxomil Potassium : 20AK00007 Chlorthalidone: 20003CT6RII		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	TR001-2/ZON-CD	TR002-2/ZON-CD	TR003-2/ ZON-CD
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	17-12-2021	17-12-2021	17-12-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 23117 Dated 16-08-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product BAXIB (Apixaban) 2.5mg and 5mg Tablets which was conducted on 05th January, 2021 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available • The firm possesses stability chambers with adequate monitoring and control.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Azilsartan Medoxomil Potassium : Copy of CoA of Batch No. 20AK00007 from M/s CTX Lifesciences (Pvt) Ltd, India is submitted. Copy of CoA of Batch No. 20AK00007 from M/s Tabros Pharma (Pvt) Ltd is submitted. Chlorthalidone: Copy of CoA of Batch No. 20003CT6RII from M/s IPCA Laboratories Ltd, India is submitted. Copy of CoA of Batch No. 20003CT6RII from M/s Tabros Pharma (Pvt) Ltd is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	Azilsartan Medoxomil Potassium: The firm has submitted copy of **accelerated, 06 Months** (25°C ± 2°C & 60±5%RH) & **long term, 48 Months** (5°C ± 3°C) stability study reports of 03 batches. Chlorthalidone: The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 65±5%RH) & **long term, 60 Months** (40°C ± 2°C, 75±5%RH) stability study reports of 03 batches.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Azilsartan Medoxomil Potassium: Copy of GMP Certificate No. 22063346 for M/s CTX Lifesciences Pvt Ltd. Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277/P, 278/P, 279 to 282, 283/P, 284/P GIDC, Sachin, Surat, Gujarat, issued by Food and Drug Administration Gujarat, India, valid till 29-05-2025 is submitted. Chlorthalidone: Copy of GMP Certificate No. V/25&28/I.C./I-53/2022/49 for M/s IPQA Laboratories Limited, PO Sejavta, Ratlam, Madhya Pradesh, issued by Food and Drug Administration Madhya Pradesh valid till 31-12-2026 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Azilsartan Medoxomil Potassium: Copy of Form-6, Form 7, Copy of Commercial Invoice No. EI/3002100489 dated 13-01-2020 cleared by ADC (Karachi) dated 25-11-2020 are submitted. Chlorthalidone: Copy of Form-6, Form 7, Copy of Commercial Invoice No. MEG2021/1633335 dated 24-02-2021 cleared by ADC (Karachi) dated 15-03-2021 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbyclor Tablet of M/s Takeda Pharmaceutical Company Limited. Firm has submitted CDP results of their product against the innovator's product Edarbyclor Tablet in 3 dissolution medi. The value for similarity factor is in the acceptable range.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[xxiii]:

Sr. No.	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	Copy of Valid Drug Manufacturing License and approval of tablet (general) section of M/s Tabros Pharma Pvt Ltd shall be submitted.	Copy of letter No. F.2-5/87-Lic (Vol-III) dated 30-06-2020 indicating renewal of Tablet (General/ General Antibiotic) section of DML No. 000106 by way of formulation w.e.f. 07-01-2020 is submitted.

	2.	Report of DML renewal/GMP inspection of the applicant within last three years shall be submitted, specifying tablet (general) section.	Firm has submitted copy of GMP Inspection report on the basis of inspection conducted on 12-12-2023 specifying tablet (general) section. The report specifies that the firm is operating at satisfactory level of GMP compliance.	
	3.	Long term stability studies of Azilsartan raw material shall be submitted for 24-month time point.	Submitted	

Decision: Approved.

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Case no. 05 Registration applications for local manufacturing of (Human) drugs (Form-5)

1096.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	KETONAZ tablet 200mg
	Composition	Each tablet contains: Ketoconazole……200mg
	Diary No. Date of R& I & fee	Dy No. 14275 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900396 dated 06-03-2019.
	Pharmacological Group	CORTICOSTEROIDS FOR SYSTEMIC USE, Anticorticosteroid ATC Code: H02CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ketoconazole 200 mg tablets MHRA Approved.
	Me-too status	KZ 200mg Tablet M/s Seraph Pharmaceutical, Islamabad Reg. No. 092348
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1097.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	EPILAP tablet 150mg
	Composition	Each film coated tablet contains: Lacosamide……150mg

	Diary No. Date of R& I & fee	Dy No. 17455 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901430 dated 06-03-2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX18 H02CA03
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Lacolep 150mg Tablet M/s Hilton Pharma (Pvt) Limited Reg. No. 73859
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Applicant has applied for Manufacturer's Specifications. Product monograph is available in BP. Change of specifications from Manufacturer's Specifications to BP is required along with relevant fee (PKR 7500/-) as per S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Approved with BP Specifications. Applicant shall submit relevant fee (PKR 7500/-) as per S.R.O 496(I)/2023 dated 17-04-2023 for change of specifications.	
1098.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	FORMIN tablet 500mg
	Composition	Each tablet contains: Metformin Hydrochloride……500mg
	Diary No. Date of R& I & fee	Dy No. 17452 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901427 dated 06-03-2019.
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30's, 50's, 100's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved.
	Me-too status	Glucophage tablet by M/s Martin Dow
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1099.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)

	Brand Name +Dosage Form + Strength	CARNIL tablet 100mg
	Composition	Each tablet Contains: Metoprolol Tartrate……100mg
	Diary No. Date of R& I & fee	Dy No. 17445 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0815570 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code: C07AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metoprolol Tartrate 100 mg film-coated Tablets. Health Canada approved
	Me-too status	Dronic 100mg Tablets, film coated. Panacea Pharmaceuticals Reg. No. 81425
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision:	
1100.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	BIRONE tablet 5mg Pack size and Demand Price 30's. As per SRO.
	Composition	Each Tablet Contains; Buspirone Hydrochloride …….5 mg
	Diary No. Date of R& I & fee	Dy No. 17422 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 815598 dated 06-03-2019.
	Pharmacological Group	Anxiolytics, Azaspirodecanedione Derivatives. ATC Code: N05BE01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Anziron 5mg Tablet M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 23872
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision:	
1101.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd

		Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	OSSORIN D tablet 400IU +830mg
	Composition	Each film coated tablet contains: Vitamin D……400 I.U Ossein Mineral Complex……830mg corresponding to: Calcium…….177.6mg* Phosphorous…….82.2mg* Residual Mineral Salts…24.8mg Collagen…224mg Other Proteins…88.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni *corresponding to approx. 440mg hydroxyapatite
	Diary No. Date of R& I & fee	Dy No. 17459 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 815561 dated 06-03-2019.
	Pharmacological Group	Mineral + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not submitted
	Me-too status	Bonmin Tablet M/s S.J & G. Fazul Ellahie (Pvt) Limited. Reg. No. 0 70532
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• ***Latest GMP inspection report is required to ascertain the availability of Atomic Absorption Spectrometer.*** • The composition of me-too product is as follows: Vitamin D…….. 400 IU Ossein Mineral Complex…830mg corresponding to Calcium…….177.6 mg Phosphorus…… 82.2mg Residual Mineral Salts……24.9mg Collagen……..224mg Other Proteins…….66.4 mg Trace elements F, Mg, Fe, Zn, Cu, Ni Firm is required to change the composition according to already approved product by DRAP, along with full fee of registration.
	Decision: Deferred. The division of PE&R was advised to check the upper limit of all the ingredients as per the Vitamin Policy of all registered product	
1102.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	NIMOWIN tablet 30mg
	Composition	Each tablet contains: Nimodipine ……200mg

	Diary No. Date of R& I & fee	Dy No. 17421 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901426 dated 06-03-2019.
	Pharmacological Group	Calcium channel blocker ATC Code: C08CA06
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved.
	Me-too status	Nidopine M/s Global Pharmaceuticals Pvt Ltd Reg. No. 028367
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	
	Decision:	
1103.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	CALCIN tablet 667mg
	Composition	Each tablet contains: Calcium acetate ……667mg
	Diary No. Date of R& I & fee	Dy No. 17429 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901405 dated 06-03-2019.
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia ATC Code: V03AE07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Lophos Tablets M/s Pharmatec Pakistan (Pvt) Ltd., Islamabad Reg. No. 031296
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1104.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	CALVIT tablet 1250mg
	Composition	Each film coated tablet contains:

		Calcium carbonate eq to 500mg elemental calcium……1250mg Vitamin D3…….125IU
	Diary No. Date of R& I & fee	Dy No. 17451 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0815565 dated 06-03-2019.
	Pharmacological Group	Vitamin D Calcium supplement
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Not found. Firm has stated Qalsan-D (Reg No. 55081) as me-too which is a chewable tablet
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for submission of following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm.**	
1105.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Liquid Ampule SVP section (General)
	Brand Name +Dosage Form + Strength	NITRO Injection 10mg/10ml
	Composition	Each 10ml ampule contains: Glyceryl Trinitrate……..10mg
	Diary No. Date of R& I & fee	Dy No. 17438 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901406 dated 06-03-2019.
	Pharmacological Group	Vasodilators used in cardiac diseases ATC Code C01DA02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	01x10ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be verified in 10ml presentation
	Me-too status	Not verifiable from available database
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: The board after delibrations rejected the application for neither having any evidence of approval of applied product in reference regulatory authority nor by DRAP (generic / me-too status) in the applied strength.	
1106.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Sterile liquid vials SVP section (General)
	Brand Name +Dosage Form + Strength	NITRO Injection 50mg/50ml
	Composition	Each 50ml vial contains: Glyceryl Trinitrate…….50mg
	Diary No. Date of R& I & fee	Dy No. 17426 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901407 dated 06-03-2019.
	Pharmacological Group	Vasodilators used in cardiac diseases ATC Code C01DA02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	01x50ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Germany approved
	Me-too status	Not found in available database
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.**	
1107.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Liquid Ampule SVP section (General)
	Brand Name +Dosage Form + Strength	BUPIVACA Spinal injection 0.75%
	Composition	Each mL ampule contains: Bupivacaine Hydrochloride ……7.5mg
	Diary No. Date of R& I & fee	Dy No. 17444 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901410 dated 06-03-2019.
	Pharmacological Group	Anaesthetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's ampules; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved product is 15mg/2mL (7.5mg/mL) injection in single dose glass ampule of 2ml
	Me-too status	Bupicaine SP Injection by M/s LCPW (Reg. No. 25856)
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General)

		Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Clarification is required for ampule size, whether it is 1ml or 2ml.
	Decision: Approved as 2ml ampule.	
1108.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Oral Liquid section (General)
	Brand Name +Dosage Form + Strength	ROSAM liquid suspension
	Composition	Each 5mL contains: Simethicone…….25mg Aluminium Hydroxide……..215mg Magnesium hydroxide…….80mg
	Diary No. Date of R& I & fee	Dy No. 17433 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0815593 dated 06-03-2019.
	Pharmacological Group	Antacids ATC Code: A02AB10
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x120mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be verified
	Me-too status	Manacid Suspension M/s. Stanely Pharmaceuticals, Peshawar Reg.no.001425
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required.
	Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority; **i. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **ii. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **iii. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **iv. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
1109.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Ear drops section (General)
	Brand Name +Dosage Form + Strength	C-DROX ear drops
	Composition	Each mL contains:

		Ciprofloxacin…… 0.3% Dexamethasone….. 0.1%
	Diary No. Date of R& I & fee	Dy No.14261 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900394 dated 06-03-2019.
	Pharmacological Group	Corticosteroids and anti-infectives in combination ATC Code: S03CA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Ciprodex Ear Drops M/s. Ethical laboratories private limited Reg.no.036261
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Pre-approval change in API from Ciprofloxacin to Ciprofloxacin Hydrochloride and revision of label claim as approved in USFDA as follows along with full fee of registration (PKR30,000) as per S.R.O 496(I)/2023 dated 17-04-2023. "Each mL suspension contains: Ciprofloxacin hydrochloride 0.3% (equivalent to 3 mg ciprofloxacin base) Dexamethasone 0.1% (equivalent to 1 mg dexamethasone)"
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: "Each mL suspension contains: Ciprofloxacin hydrochloride 0.3% (equivalent to 3 mg ciprofloxacin base) Dexamethasone 0.1% (equivalent to 1 mg dexamethasone)".	
1110.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name +Dosage Form + Strength	ROXIDIL LOTION 5% (w/v)
	Composition	Each mL contains: Minoxidil ……...50mg
	Diary No. Date of R& I & fee	Dy No.14067 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 0142541 dated 07-03-2019.
	Pharmacological Group	Other dermatological preparations ATC Code: D11AX01
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Manufacturer's Specifications; Monograph of Topical solution is available in USP
	Pack size & Demanded Price	60mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MINOXIDIL EXTRA STRENGTH (FOR MEN). MINOXIDIL EXTRA STRENGTH (FOR WOMEN). USFDA approved as OTC product (2% w/v topical solution)
	Me-too status	Regro Solution 2% & 5% M/s. Seattle Pvt Ltd

	GMP status	Lotion section is not included in latest GMP certificate issued to the firm.
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility / section (External liquid preparation/lotion; general) from Licensing Division DRAP is required. • Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section. • Change the composition from Minoxidil 50mg/mL to Monixidil 20mg/mL as per product approved in USFDA along with full fee of registration (PKR30,000) vide S.R.O 496(I)/2023 dated 17-04-2023. • Revision of label as follows: "ROXIDIL Topical Solution 2% (w/v) Each mL contains: Minoxidil ……...20mg"
	Decision: Deferred for submission of response to above-cited shortcomings.	
1111.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name +Dosage Form + Strength	BEAT LOTION 0.05% (w/v)
	Composition	Each mL contains: Betamethasone Dipropionate ……...0.5mg
	Diary No. Date of R& I & fee	Dy No.14069 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 0610399 dated 07-03-2019.
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20mL & 60mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved; Each gram of DIPROSONE Lotion 0.05% w/w Contains: 0.643 mg Betamethasone Dipropionate, USP (equivalent to 0.5 mg betamethasone)
	Me-too status	Effidex Lotion M/s. Mass Pharma (Pvt) Ltd Reg. No. 64613
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility / section (External liquid preparation; general/steroidal) from Licensing Division DRAP is required. • Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section. • Evidence of separate dispensing facility for dispensing of steroidal raw materials. • Change in quantity of active (betamethasone dipropionate) in master formulation and revision of label as follows as per reference product, along with full fee of registration (PKR30,000) vide S.R.O 496(I)/2023 dated 17-04-2023: "Each mL contains: Betamethasone Dipropionate equivalent to Betamethasone ……...0.5mg"
	Decision: Deferred for submission of response to above-cited shortcomings.	
1112.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd

		Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name +Dosage Form + Strength	BEAT-D LOTION 0.05% (w/v)
	Composition	Each mL contains: Betamethasone Dipropionate ……...0.5mg Clotrimazole…….10mg
	Diary No. Date of R& I & fee	Dy No.14064 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 0142542 dated 07-03-2019.
	Pharmacological Group	Imidazoles/triazoles in combination with corticosteroids ATC Code D01AC20
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	25mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as follows Each mL contains: Betamethasone Dipropionate equivalent to Betamethasone ……0.5mg Clotrimazole…….10mg
	Me-too status	Not found in applied strength or as per reference product
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. • Evidence of required manufacturing facility / section (External liquid preparation; general/steroidal) from Licensing Division DRAP is required. • Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section. • Evidence of separate dispensing facility for dispensing of steroidal raw materials. • Quantity of APIs on Form 5 is Betamethasone Dipropionate 0.5mg/ml and Clotrimazole 10mg/ml whereas quantity given in master formulation is 12.5mg/ml and 250mg/ml respectively. Revised quantity of APIs is required according to reference product along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for submission of response to above-cited shortcomings.	
1113.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name +Dosage Form + Strength	BEAT-S LOTION 0.05% (w/v)
	Composition	Each mL contains: Betamethasone Dipropionate ……...0.5mg Salicylic acid……3mg
	Diary No. Date of R& I & fee	Dy No.14071 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 0610390 dated 07-03-2019.
	Pharmacological Group	Betamethasone and antiseptics ATC Code D07BC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	25mL & 60mL ; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Not found
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. • Evidence of required manufacturing facility / section (External liquid preparation; general/steroidal) from Licensing Division DRAP is required. • Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section. • Evidence of separate dispensing facility for dispensing of steroidal raw materials is required. • Quantity of APIs on Form 5 is Betamethasone Dipropionate 0.5mg/ml and salicyclic acid 3mg/ml whereas quantity given in master formulation is 12.5mg/ml and 750mg/ml respectively. Revised quantity of APIs is required according to reference product (if any) along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for submission of response to above-cited shortcomings.	
1114.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)
	Brand Name +Dosage Form + Strength	CLINDEX LOTION 1% (w/v)
	Composition	Each mL contains: Clindamycin (as phosphate) ……...10mg
	Diary No. Date of R& I & fee	Dy No.14066 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 0610387 dated 07-03-2019.
	Pharmacological Group	Antiinfectives for treatment of acne ATC Code D10AF01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Veclin-T Lotion M/s. Shrooq Pharmaceuticals Reg. No. 100599
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility / section (External liquid preparation; general antibiotics) from Licensing Division DRAP is required. • Latest GMP inspection report is required (inspection should have been conducted within last three years) clearly mentioning relevant section.
	Decision: Deferred for submission of response to above-cited shortcomings.	
1115.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)

		Cream/ointment (General)
	Brand Name +Dosage Form + Strength	CLINCIN CREAM 2% (w/v)
	Composition	Each mL contains: Clindamycin (as phosphate) ……...20mg
	Diary No. Date of R& I & fee	Dy No.14286 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1901259 dated 07-03-2019.
	Pharmacological Group	Antibiotics ATC Code G01AA10
	Type of Form	Form 5
	Finished Product Specification	USP; vaginal cream
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clindesse cream, USFDA approved
	Me-too status	Ceda-V 2% Vaginal Cream M/s. Fynk Pharmaceuticals Reg. No. 74989
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1116.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	CENICOL EYE DROPS 0.5% (w/v)
	Composition	Each mL contains: Chloramphenicol …….....0.5%
	Diary No. Date of R& I & fee	Dy No.14271 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900405 dated 06-03-2019.
	Pharmacological Group	Antiinfectives ATC Code S02AA01
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic solution
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found; Cancelled post market by Health Canada
	Me-too status	Chlorin Eye drops M/s. NovaMed Pharmaceuticals (Pvt) Ltd Reg. No. 84887
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Change in label claim to read: Each mL contains:

		Chloramphenicol …….....5mg, along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 for pre-registration change in composition.
	Decision: Deferred for submission of response to above-cited shortcomings.	
1117.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	ROBATEX OPTHALMIC SUSPENSION
	Composition	Each 5mL contains: Betaxolol HCl as Betaxolol……0.5% (w/v)
	Diary No. Date of R& I & fee	Dy No.16801 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1901299 dated 06-03-2019.
	Pharmacological Group	Beta blocking agent ATC Code S01ED02
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic solution
	Pack size & Demanded Price	5mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied strength is USFDA approved as Ophthalmic solution instead of suspension
	Me-too status	Betaxolol 0.5% M/s. Invotek Reg. No. 026956
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	• Master formulation includes Betaxolol instead of Betaxolol Hydrochloride. Change the master formulation to include salt form of Betaxolol in the required quantity and change label claim according to reference product as follows: "Rotadex ophthalmic solution Composition: Betaxolol hydrochloride equivalent to Betaxolol …….....0.5% w/v" along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 for pre-registration change in composition.
	Decision: Approved. Applicant shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim and master formulation as follows: **"Rotadex ophthalmic solution** **Composition:** **Betaxolol hydrochloride equivalent to Betaxolol …….....0.5% w/v".**	
1118.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	HYPODEX EYE DROPS
	Composition	Each mL contains: Dextran 70.…….....0.1% w/v

		Hypromellose…….0.3%w/v
	Diary No. Date of R& I & fee	Dy No.16807 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900424 dated 06-03-2019.
	Pharmacological Group	Lubricant and artificial tears
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications; ophthalmic solution
	Pack size & Demanded Price	15mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Ashk Eye Drops M/s. Ray Pharma (Pvt.) Ltd Reg. No. 76593
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of PKR7500/- fee for revision of specifications as per notification No.496(I)/2023 dated 17-04-2023.	
1119.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	MEROTEX EYE DROPS 0.1% (w/v)
	Composition	Each mL contains: Flurometholone …….....1mg
	Diary No. Date of R& I & fee	Dy No.14273 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900409 dated 06-02-2019.
	Pharmacological Group	Corticosteroids/antiinfectives/mydriatics in combination ATC Code S01CB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5mL, 10mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Flouramet Ophthalmic Suspension M/s. Pharmasol (Pvt) Ltd, Lahore. Reg. No. 90430
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Master formulation includes Flurometholone instead of Flurometholone acetate. Change the master formulation to include Flurometholone acetate in the required quantity and change label claim according to reference product as follows: "Composition: Flurometholone acetate equivalent to Flurometholone 0.1% (w/v)," along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 for pre-registration change in composition.
	Decision: Approved. Applicant shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: **"Composition:** **Flurometholone acetate equivalent to Flurometholone 0.1% (w/v)".**	
1120.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)

	Brand Name +Dosage Form + Strength	TRMIDE EYE DROPS 1% (w/v)
	Composition	Each mL contains: Tropicamide …….....10mg
	Diary No. Date of R& I & fee	Dy No.14260 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900393 dated 06-03-2019.
	Pharmacological Group	Anticholinergics ATC Code S01FA06
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic solution
	Pack size & Demanded Price	10mL, 15mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Mydriacyl (USFDA Approved)
	Me-too status	Troposol Ophthalmic Solution M/s. Pharmasol (Pvt) Ltd, Lahore Reg. No. 90428
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1121.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	BRINZO OPTHALMIC SUSPENISON 0.5% (w/v)
	Composition	Each mL contains: Brinzolamide …….....10mg
	Diary No. Date of R& I & fee	Dy No.14262 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900417 dated 06-03-2019.
	Pharmacological Group	Carbonic anhydrase inhibitors ATC Code S01EC04
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic suspension
	Pack size & Demanded Price	5mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Azopt (Ophthalmic Suspension) Eye Drops M/s. Novartis Pharma (Pakistan) Limited Reg. No. 91909
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1122.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	ROTIM EYE DROPS 1% (w/v)
	Composition	Each mL contains: Timolol maleate …….....0.5%
	Diary No. Date of R& I & fee	Dy No.16789 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900497 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents ATC Code S01ED01
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic solution

	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (timolol as maleate)
	Me-too status	Optipress 5mg Eye Drops M/s. ETHICAL LABORATORIES PRIVATE LIMITED, Lahore Reg. No. 45579
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Pre-registration change for equivalency of weight and adjustment as per salt factor (revision from Timolol maleate to Timolol (as maleate) and change of label claim according to reference product are required as follows: "Composition: Timolol maleate equivalent to Timolol 0.5% (w/v)," along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: **"Composition:** **Timolol maleate equivalent to Timolol 0.5% (w/v)".**	
1123.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	ANROST-M EYE DROPS
	Composition	Each mL contains: Latanoprost …….....50mcg Timolol Maleate……..5mg
	Diary No. Date of R& I & fee	Dy No.14277 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900403 dated 06-03-2019.
	Pharmacological Group	Timolol (beta blocking agent), combinations ATC Code S01ED51
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	2.5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Latmo Eye Drops M/s. Shaigan Pharmaceuticals (Pvt) Ltd Reg. No. 48976
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1124.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	TAMACIN OPTHALMIC SUSPENSION
	Composition	Each mL contains: Netilmicin sulphate equivalent to Netilmicin …….....0.3mg
	Diary No. Date of R& I & fee	Dy No.14280 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900399 dated 06-03-2019.
	Pharmacological Group	Antibiotics ATC Code S01AA23
	Type of Form	Form 5

	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	N-Cin Eye Drops M/s. Hygeia Pharmaceuticals, Plot No. 295 Industrial Triangle Kahuta Road Islamabad. Reg. No. 77714 (Suspension form is not confirmed)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required.
	Decision: Deferred for submission of evidence of approval of applied product in reference regulatory authority.	
1125.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	BRIMOLOL EYE DROPS
	Composition	Each mL contains: Brimonidine Tartarate …….....0.2%w/v Timolol (as maleate)……...0.5% w/v
	Diary No. Date of R& I & fee	Dy No.14278 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900416 dated 06-03-2019.
	Pharmacological Group	Timolol (beta blocking agent), combinations ATC Code S01ED51
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Brimogan Ophthalmic Solution M/s. M/s Helix Pharma (Pvt)., Ltd Reg. No. 75934
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved. Firm shall submit PKR 7500/- for change in specifications as per notification No.496(I)/2023 dated 17-04-2023.	
1126.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	H-OPTIC EYE DROPS
	Composition	Each mL contains: Hypromellose …….....0.5%
	Diary No. Date of R& I & fee	Dy No.14282 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1901288 dated 06-03-2019.
	Pharmacological Group	Artificial tears and other indifferent preparations ATC Code S01XA20
	Type of Form	Form 5
	Finished Product Specification	USP; ophthalmic solution
	Pack size & Demanded Price	10mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Not found in applied strength

	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. • Quantity of API in Master formulation is 10mg/mL. Change in quantity of API in master formulation is required as per reference product with the following label claim: "Compostion: Hypromellose……0.5%(w/v)", along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023. for pre-registration change in composition.
	Decision: Deferred for submission satisfactory response to the afore-mentioned shortcomings.	
1127.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General/Steroidal)
	Brand Name +Dosage Form + Strength	FUSE EYE DROPS
	Composition	Each mL contains: Fusidic acid …….....1%
	Diary No. Date of R& I & fee	Dy No.14268 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900426 dated 06-03-2019.
	Pharmacological Group	Antibiotics ATC Code S01AA13
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Fucid Eye Drops M/s. Hygeia Pharmaceuticals, Plot No. 295 Industrial Triangle Kahuta Road Islamabad. Reg. No. 77713
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Change in label claim to read: Each mL contains: Fusidic acid …….....10mg, along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 for pre-registration change in composition.
	Decision: Deferred for submission satisfactory response to the afore-mentioned shortcomings.	
1128.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	TOBRACIN EYE DROPS
	Composition	Each mL contains: Tobramycin …….....0.3%w/v
	Diary No. Date of R& I & fee	Dy No.14276 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900402 dated 06-03-2019.
	Pharmacological Group	Antibiotics ATC Code S01AA12

	Type of Form	Form 5
	Finished Product Specification	USP; Ophthalmic solution
	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	ORBACIN 0.3% eye drops by M/s Zafa Pharma, Reg. No. 20200
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1129.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	KAFIT EYE DROPS
	Composition	Each mL contains: Ketotifen Fumarate 0.345mg equivalent to ketotifen……0.25mg
	Diary No. Date of R& I & fee	Dy No.16800 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900404 dated 06-03-2019.
	Pharmacological Group	Other Antiallergics ATC Code S01GX08
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	5mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ketti Eye Drops M/s. Innvotek Pharmaceuticals Reg. No. 81416
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Master formulation includes Ketotifen instead of Ketotifen fumarate. Change the master formulation to include salt form of Ketotifen along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 for change in API from base to salt form.	
1130.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Eye drops (General)
	Brand Name +Dosage Form + Strength	ZOLAMINE EYE DROPS
	Composition	Naphazoline Hydrochloride……..0.025% Pheniramine Maleate……0.3%
	Diary No. Date of R& I & fee	Dy No.14281 dated 07-03-2019 Fee paid PKR20,000/-vide Deposit Slip No. 1900418 dated 06-03-2019.
	Pharmacological Group	Sympathomimetics used as decongestants ATC Code S01GA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	15mL; as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as OTC product
	Me-too status	Naph P EyeDrops

		M/s. Jaens Pharmaceutical Industries Pvt ltd. Reg. No. 110861
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Revise the quantities of APIs in the master formulation according to the label claim, along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall revise the quantities of APIs in the master formulation according to the label claim, along with full fee of registration (PKR30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023.	

Case no. 06 Registration applications for local manufacturing of (veterinary) drugs

a. Deferred Cases

1131.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	MIL-D-FAR INJECTION
	Composition	Each ml Contains: Calcium Gluconate…208.3mg Calcium D-Sacharate…10mg Magnesium Hypophosphite…53.3mg Magnesium Chloride…20mg Boric Acid…43.3mg Dextrose…200mg Vitamin B1…1mg Vitamin B2…0.7mg Vitamin B12…30mcg Nicotinamide…2mg
	Diary No. Date of R& I & fee	Dy.No 31318 dated 12-11-2021 Rs.30,000/- dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 039497054842
	Pharmacological Group	Electrolytes/Minerals/Antidotes/Multivitamins
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	300ml vial; Decontrolled
	Me-too status	Not found in available record
	GMP status	As above
	Previous remarks of the Evaluator[xxiii].	Firm was advised to provide, inter alia, the following vide letter No. F.2-1/2023/ PEC-DRAP (DD-PEC-XXIII) dated 04-07-2023: "Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, pack size, brand name and name of firm." Reply of applicant was submitted vide letter No. IZF/DRAP-PEC/JUL-23-04 dated 07-07-2023 (Dy No. 17153 dt 10-07-2023), stating **Mil-D Forte Injection (Reg. No. 007629) by M/s Star Laboratories, Lahore** as the me-too product. However, the same could not be confirmed from available database. Firm may be advised to provide some other me-too/ generic.
	Decision of 330th meeting of RB	Deferred for submission of following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with

		registration number, pack size, brand name and name of firm. • Evidence of relevant manufacturing facility. The Board further decided that the applicant shall submit response within 1 month after publication of the minutes.
	Reply of Applicant	Reply of applicant was submitted vide Ref. No. IZF/NDR/12-02 dated 13-02-2024. Applicant has stated that there was a typographical error in applied formulation. Instead of Vitamin B2….0.70mg, the composition includes Vitamin B6….0.7mg. Me-too: **Mil-D Forte Injection (Reg. No. 007629) by M/s Star Laboratories, Lahore**
	Remarks of the Evaluator[xxiii].	Applicant shall submit prescribed fee (PKR30,000) for change in composition. Applicant has once again submitted reference of **Mil-D Forte Injection (Reg. No. 007629) by M/s Star Laboratories, Lahore** as the me-too product which cannot be verified from available database. Evidence of relevant manufacturing facility i.e. manufacturing of LVP and its approval from Licensing Division of DRAP is not submitted. Jutify the solubility of hyphophite form in the formulation.
	Decision: Deferred for submission of satisfactory response to above-cited shortcomings.	
1132.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	MILFAR-C INJECTION
	Composition	Each ml Contains: Calcium Gluconate…208.3mg Calcium D Sacharate…10mg Magnesium Hypophosphite…53.3mg Magnesium Chloride…20mg Boric Acid…43.3mg Dextrose…200mg
	Diary No. Date of R& I & fee	Dy.No 31322 dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No.769136104014
	Pharmacological Group	Electrolytes/Minerals/Antidotes
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	300ml, 450ml glass vial; Decontrolled
	Me-too status	Milphone-C injection (300ml) M/s Star Laboratories, Lahore Reg. No. 003794
	GMP status	As above
	Previous remarks of the Evaluator[xxiii].	• Firm was advised to provide, inter alia, the following vide letter No. F.2-1/2023/ PEC-DRAP (DD-PEC-XXIII) dated 04-07-2023: "Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the applied fill volume** along with registration number, pack size, brand name and name of firm." Reply of applicant was submitted vide letter No. IZF/DRAP-PEC/JUL-23-05 dated 07-07-2023 (Dy No. 17152 dt 10-07-2023), stating **Milfone-C (Reg. No. 003794)** as the me-too product. According to the available office record, the me-too product is available

		in 300ml with different composition than the applied product. Accordingly, revision of pack size, change in master composition and label claim as follows according to product already approved by DRAP is required, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: Calcium Gluconate 65.83mg Calcium D Saccharase 3.33mg Magnesium Hypophosphate 16.67mg Magnesium Chloride 3.33mg Magnesium Hypophosphate 16.67mg Magnesium Chloride 3.33mg Boric Acid 14.1mcg Dextrose 66.67mcg"
	Decision of 330th meeting of RB	**Deferred for submission of following:** • **Confirmation of LVP manufacturing facility** • **Justification of the applied formulation regarding the concentrations of ingredients per ml.**
	Reply of Applicant	Reply of applicant has been submitted vide Ref. No. IZF/NDR/12-02 dated 13-02-2024.
	Remarks of the Evaluator[xxiii].	Applicant has not submitted satisfactory response to above-mentioned shortcomings.
	Decision: Deferred for submission of satisfactory response to above-cited shortcomings.	

Case no. 07 Registration applications of import cases

a. Deferred cases

i. Veterinary

1133.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32050 Dated 23-11-2021
	Fee including differential fee	Rs. 75,000 Deposit Slip No. 69546034807
	Brand Name +Dosage Form + Strength	FLOFENICOL 20% ORAL SOLUTION
	Composition	Each ml contains: Florfenicol…200mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled

	Pack size	50ml,100ml, 150ml, 250ml,500ml, 1L, 2L, 5L
	International availability	Florfenicol 20% Oral Reg. No.THQ-119-XK Registered in Vietnam Validity: 23-11-2022
	Me-too status	Floricol Liquid M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. Reg. No. 073936 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP

		(DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 09219320350. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states**

		that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision: Deferred for the Verification of "Sole Agency Agreement" through email..	
1134.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32060 Dated 23-11-2021

	Fee including differential fee	Rs.75,000 Deposit Slip No. 232268028
	Brand Name +Dosage Form + Strength	PRO-CRD COMPLEX 30/20 WATER SOLUBLE POWDER
	Composition	Each gram powder contains: - Tylosin Tartrate…….200mg Doxycycline HCl……...400 mg Colistin Sulphate…....1MIU Bromhexine HCl…….10 mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g, 500g, 1kg, 5kg, 20kg, 25kg
	International availability	PRO-CRD Complex 30/20 Reg. No.THQ-220-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	MONODOXWATER SOLUBLE POWDER M/s BAARIQ PHARMACEUTICALS, LAHORE Reg. No. 087142
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

		• Revised label • Differential fee of Rs.75000 vide Deposit slip No. 528225379. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied

		formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision: Deferred for the Verification of "Sole Agency Agreement" through email..	
1135.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32058 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 66484026
	Brand Name +Dosage Form + Strength	Para Plus Oral Powder
	Composition	Each 100gm Contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm"
	Finished Product Specification	Not stated
	Pharmacological Group	Antipyretic, Multivitamin
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg,25kg
	International availability	Para plus Reg. No.THQ-185-XK Registered in Vietnam Validity: 25-02-2022
	Me-too status	Parascorbic powder M/s Baariq Pharmaceuticals, Lahore. Reg. No. 087190
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years

		(Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for*

		oral use. • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 24778999902. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether**

		the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP). **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	Review of Sub-committee on Veterinary Drugs is awaited regarding therapeutic requirement keeping in view safety, efficacy and quality parameters
	Decision: Deferred for the Verification of "Sole Agency Agreement" through email..	
1136.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32059 Dated 23-11-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 43403191338
	Brand Name +Dosage Form + Strength	Tilmicosin Oral Solution
	Composition	Each ml Contains: Tilmicosin Phosphate…250mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic

	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 150ml, 250ml,500ml, 1L, 2.5L
	International availability	Tilmicosin Reg. No.THQ-137-XK Registered in Vietnam Validity: 24-3-2022
	Me-too status	Tilmicobak Oral Liquid M/s Attabak Pharma. Reg.No.075706
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required.

		The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 48617838. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.**	
1137.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate:

		Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32061 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 5035508680
	Brand Name +Dosage Form + Strength	Pro-Lamox-C WSP
	Composition	Each 100gm Contains: Amoxicillin Trihydrate…20gm Colistin Sulphate…50MIU
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	Pro-Lamox-C Reg. No.THQ-221-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Fagomox M/s Farm Aid Group Reg. No. 087189
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or

		USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 973258620415. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of

		non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules.
	Decision: Deferred for **i. submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders and** **ii. Vrification of letter of authorization through e-mail**	
1138.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32062 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 474201420
	Brand Name +Dosage Form + Strength	Pro-Cefo Injection
	Composition	Each ml Contains: Ceftiofur as HCl…50mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Pro-Cefo Injection Reg. No.THQ-239-XK Registered in Vietnam Validity: 18-12-2022
	Me-too status	Exefur Injection M/s SJ&G FazulEllahie Reg. No. 063704 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist

		Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Cephalosporin Injectables* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for

		five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 5425865744. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*.**

		• **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for cephalosporin dosage form as required under LRA Rules 1976.
	Decision: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of Cephalosporin injectables and verification of letter of authorization through e-mail.	
1139.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32063 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 9365242748

	Brand Name +Dosage Form + Strength	Pro-Liso 4.4% Feed Premix Powder
	Composition	Each 100gm Contains: Lincomycin HCl…4.4gm
	Finished Product Specification	Not stated; Lincomycin HCl soluble powder is available in USP
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,500g, 1kg,10kg, 5kg, 25kg
	International availability	Pro-Liso 4.4% THQ-222-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Lincos-P Powder M/s A&K Pharmaceuticals. Reg. No. 049667 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between

		manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 251517196. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be

		provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. USP Specifications
	Remarks of evaluator[xxiii]	
	Decision: Deferred for verification of letter of authorization through e-mail.	
1140.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad,

		Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32054 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 224432818225
	Brand Name +Dosage Form + Strength	Super T.D Man-70% WSP
	Composition	Each 100gm Powder Contains: Doxycycline Hyclate Eq. to 800gm of Doxycycline…923.32gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,250g,500g, 1kg, 5kg,20kg, 25kg
	International availability	Super T.D Man -70% Reg. No.THQ-224-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Doxyral 80% powder M/s Orient Animal Health Reg. No. 082504 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung

		Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the

		manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 54195176543. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years

		from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.**	
1141.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32053 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 3266953570
	Brand Name +Dosage Form + Strength	Super Lamox-70% WSP
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…700gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50g,100g, 250g,500g, 1kg, 5kg, 10kg
	International availability	Super Lamox-70% Reg. No.THQ-223-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Primox 70% WSP M/s Prix Pharma Reg. No. 074032
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam

		in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder for solution.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business".

		• Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 0156607334. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be**

		provided by the issuing authority of the Free Sales Certificate. • **Legalized copy of valid GMP certificate of the manufacturer**. • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders.	
1142.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32064 Dated 23-11-2021

	Fee including differential fee	Rs.75,000 Deposit Slip No. 468627042483
	Brand Name +Dosage Form + Strength	ProZSB Plus Powder
	Composition	Each 1000gm Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	ProZSB Plus Reg. No.THQ-219-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	PSB 100 M/s Epla Labs Reg. No. 013257
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e.*

		Penicillin Oral Powder. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 2515097727. Following are still required: • Free Sales Certificate for the applied product in the

		country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral;

		Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders.	
1143.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32052 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 74459177223
	Brand Name +Dosage Form + Strength	Flunixin 5% Injection
	Composition	Each ml Contains: Flunixin Meglumine…50mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Flunixin 5% Injection Reg. No.THQ-149-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Maxin Injection M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reg. No. 043576(10ml,20ml,50ml, 100ml)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement**

		Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales

		Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 973993467. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house**

		Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP). **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. USP Specifications
	Remarks of evaluator[xxiii]	
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.**	
1144.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32056 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 5803348191
	Brand Name +Dosage Form + Strength	Proaminovit Injection
	Composition	Each ml Contains: Dextrose (Glucose)...50mg Calcium Chloride...2mg Potassium Chloride...2mg

		Magnesium Sulphate...2mg Sodium Acetate...7.5mg L-Histidine HCl...0.02mg DL-Methionine...0.525mg L-Tryptophan...0.175mg L-Cysteine HCl...0.02mg L-Threonine...0.35mg L-Isoleucine...0.525mg L-Arginine HCl...1.425mg L-Phenylalanine...0.35mg L-Valine...0.525mg L-Lysine...0.525mg L-Leucine...0.6mg Monosodium Glutamate...0.08mg Riboflavin...0.05mg D-Panthenol...0.1mg Pyridoxine HCl...0.1mg Nicotinamide...3mg Thiamine HCl...0.1mg
	Finished Product Specification	Not stated
	Pharmacological Group	Multivitamims
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	250ml
	International availability	Pro Amino Vit Reg. No.THQ-90-XK Registered in Vietnam Validity: 23-11-2022
	Me-too status	Could not be verified from available database
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can

		Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the

		finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 79993318292. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Provision of legalized Free Sale Certificate indicating the product is licensed and on marlet in country of origin as submitted Free Sale indicates the product is not licensed and is for export only.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines

		of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	Me-too status: Aminovital High Injection Reg. No. 020083 Sole distributor: Atzaan Pharmaceuticals, Sargodha. Composition on marketed pack size is the same as the applied product however, the composition cannot be verified from the available database.
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.**	
1145.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32055 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 24737481
	Brand Name +Dosage Form + Strength	Enrofloxacin 10% Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…50MIU
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 500ml, 1L, 5L
	International availability	Enrofloxacin 10% THQ-164-XK Registered in Vietnam Validity: 20-05-2021
	Me-too status	Reg No.074080 AMTIN-C ORAL LIQUID M/S. D-MAARSON PHARMACEUTICALS, PLOT # 17, STREET SS-2, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are

		registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 346346776. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.**

		• **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.**	
1146.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32051 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 20964369

	Brand Name +Dosage Form + Strength	Fos-T Oral Powder
	Composition	Each 1000gm Contains: Fosfomycin Calcium…200gm Tylosin Tartrate…100gm Fructose 1,6 Diphosphate…180gm Sodium Phosphate…150gm Magnesium Sulphate…100gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg,25kg
	International availability	Fos T Reg. No.THQ-182-XK Registered in Vietnam Validity: 13-07-2023
	Me-too status	Reg. No.113592 FAS-FO 73 POWDER M/s Eterna Pharma (Pvt) Ltd., Plot # 99,100,101&198- C, Sector D1, Old Industrial Estate, Mirpur, AJK.
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is

		different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm is required. If me-too is available, differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Me-too status provided • Differential fee of Rs.75000 vide Deposit slip No. 57653080426. Following are still required:

		• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications

	Remarks of evaluator[xxiii]	
	Decision:. Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.** **The registration letter will be issued after submission of target species and indications**	
1147.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32057 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 4446146165
	Brand Name +Dosage Form + Strength	Pollo-CRD Plus Oral Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Colistin Sulphate…450MIU Bromhexine HCl…5gm Streptomycin Sulphate…36gm
	Finished Product Specification	Not stated
	Pharmacological Group	Mucolytic, Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 20kg,25kg
	International availability	Pollo-CRD Plus Reg. No.THQ-218-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Reg No.071069 PULMODOX-S POWDER ATTABAK PHARMACEUTICAL, ISLAMABAD.
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years

		(Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for*

		oral use. • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 79682450386. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision of 330th meeting of RB:	**Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product**

		• **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	• Review of Sub-committee on Veterinary Drugs is awaited regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs is awaited regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Case No. 08
MISCELLANEOUS CASES

Following one application case was considered and approved in 333rd meeting of Registration Board conducted on 19-20th December, 2023 but the decision was recorded incorrect. Presented for the correction in recording of minutes.

1148.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	DESVEN tablet 50mg
	Composition	Each film coated tablet contains: Desvenlafaxine…..... 50mg
	Diary No. Date of R& I & fee	Dy No. 14608 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792399 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX23
	Type of Form	Form 5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Extended release tablet (DIN 02535106) is Health Canada approved.

	Me-too status	Desven XR 50mg Tablet (For extended release tablet) Pharmevo (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are not provided. • Applied product is film coated tablet. Formulation approved in reference regulatory authority (Health Canada) and in Pakistan is extended release tablet. Change in formulation from film coated to extended release tablet along with relevant fee is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Latest GMP inspection report conducted within last three years.** • **Provision of finished product specifications.** • **Change in formulation from film coated to extended release tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Finished product complies Manufacturer's Specifications. • Formulation changed from film coated to extended release tablet as available in reference regulatory authority along with Rs.7500/- fee vide DS No. 05302223173.
	Remarks of the Evaluator[xxiii].	Differential fee (PKR 22,500/-) shall be submitted by applicant as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition.
	Decision: Approved with following label claim with Manufacturer's specifications: **"Each film coated tablet contains:** **Desvenlafaxine ..... 50mg."** **Applicant shall submit Rs. 22,500/- differential fee for pre-registration correction of composition, before issuance of registration letter.**	

The decision of the Board was erroneously recorded as follows:

"Approved with following label claim with Manufacturer's specifications:

"Each film coated tablet contains:

Desvenlafaxine .....50mg."

Applicant shall submit Rs. 22,500/- differential fee for pre-registration correction ofcomposition, before issuance of registration letter."

Whereas the decision is as follows:

"Approved with following label claim with Manufacturer's specifications:

"Each extended release tablet contains:

Desvenlafaxine .....50mg."

Applicant shall submit Rs. 22,500/- differential fee for pre-registration correction ofcomposition, before issuance of registration letter."

Submitted for consideration by the Board, please.

Decision: Registration Board decided to correct the decision of above case as follows:

"Approved with following label claim with Manufacturer's specifications:
"Each extended release tablet contains:
Desvenlafaxine .....50mg."
Applicant shall submit Rs. 22,500/- differential fee for pre-registration correction of composition, before issuance of registration letter."

Agenda of Evaluator PEC-XXIV

Agenda for applications submitted on Form 5F for Import
Anticancer: Cases marked and evaluated on the basis of decision of 257th meeting of Registration Board.

1149.	Name, address of Applicant / Importer	M/s: AJM Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Karachi.
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/149 Address: 1st Floor, Shafi Court, Merewether Road, Karachi. Address of Godown: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22-02-2028. Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India
	Name, address of manufacturer(s)	Intas Pharmaceuticals Limited, Plot Nos. 5-14, Pharmez Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat, 382213, India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: HD3-OEE-G4LG: 10-05-2024
	Details of fee submitted	PKR 300,000/-: 03-05-2024
	The proposed proprietary name / brand name	**Dasatinib 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 20mg tablet contains: Dasatinib …….20mg
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	Manufacturer's specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP (No. MFG/WHO GMP/COPP/2023/8930235520) dated 24-08-2023, valid till 27-02-2026 issued by Food & Drug Control Administration Gujrat state-Gandhinagar, India. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted Contract of Agency between Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej,

		Ahmedabad – 380054, Gujarat, INDIA and AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi, dated 23-04-2024.
	The status in reference regulatory authorities	SPRYCEL® film-coated tablet 20mg Bristol-Myers Squibb Pharma EEIG, Ireland.
	For generic drugs (me-too status)	Dasanix 20mg tablet of Himmel Pharmaceutical
	Proposed unit price	As Per SRO.

Evaluation by PEC (XXIV):

Sr. No.	Section	Observations	Reply of the Firm
1	1.3.3	Legalized/Embassy attested and notarized CoPP shall be submitted.	Submitted.
2	3.2.P.2.1	Pharmaceutical equivalence studies data, report and CDP profile shall be submitted.	Firm has submitted Pharmaceutical equivalence and CDP stuies of the product with Sprycel 20mg Tablet (Bristol-Myers Squibb).

Decision: Approved as per Policy for inspection of Manufacturer abroad.

1150.	**Name, address of Applicant / Importer**	M/s: AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Karachi.
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/149 Address: 1st Floor, Shafi Court, Merewether Road, Karachi. Address of Godown: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22-02-2028. Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India
	Name, address of manufacturer(s)	Intas Pharmaceuticals Limited, Plot Nos. 5-14, Pharmez Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat, 382213, India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: 6A4-41B-DNJ3: 20-05-2024
	Details of fee submitted	PKR 300,000/-: 03-05-2024
	The proposed proprietary name / brand name	**Dasatinib 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50mg tablet contains: Dasatinib …….50mg
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	Manufacturer's specification

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Relevant CoPP and Free Sale certificate not submitted.
	Details of letter of authorization / sole agency agreement	Firm has submitted Contract of Agency between Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, INDIA and AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi, dated 23-04-2024.
	The status in reference regulatory authorities	SPRYCEL® film-coated tablet 50mg Bristol-Myers Squibb Pharma EEIG, Ireland.
	For generic drugs (me-too status)	Dasanix 50 mg tablet of Himmel Pharmaceutical
	Proposed unit price	As Per SRO.

Evaluation by PEC (XXIV):

Sr. No.	Section	Observations	Reply of the Firm
1	1.3.3	Relevant Legalized/Embassy attested and notarized CoPP shall be submitted.	Submitted.
2	3.2.P.2.1	Pharmaceutical equivalence studies data, report and CDP profile shall be submitted.	Firm has submitted Pharmaceutical equivalence and CDP stuies of the product with Sprycel 50mg Tablet (Bristol-Myers Squibb).

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

1151.	**Name, address of Applicant / Importer**	M/s: AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Karachi.
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/149 Address: 1st Floor, Shafi Court, Merewether Road, Karachi. Address of Godown: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22-02-2028. Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India
	Name, address of manufacturer(s)	Intas Pharmaceuticals Limited, Plot Nos. 5-14, Pharmez Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat, 382213, India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: 2R2-BT8-ZYT1: 14-05-2024
	Details of fee submitted	PKR 300,000/-: 03-05-2024

	The proposed proprietary name / brand name	**Dasatinib 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mg tablet contains: Dasatinib …….100mg
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	Manufacturer's specification
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Relevant CoPP and Free Sale certificate not submitted.
	Details of letter of authorization / sole agency agreement	Firm has submitted Contract of Agency between Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, INDIA and AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi, dated 23-04-2024.
	Proposed unit price	As Per SRO.
	The status in reference regulatory authorities	SPRYCEL® film-coated tablet 100mg Bristol-Myers Squibb Pharma EEIG, Ireland.
	For generic drugs (me-too status)	Dasanix 100 mg tablet of Himmel Pharmaceutical

Evaluation by PEC (XXIV):

Sr. No.	Section	Observations	Reply of the Firm
1	1.3.3	Relevant Legalized/Embassy attested and notarized CoPP shall be submitted.	Submitted.
2	3.2.P.2.1	Pharmaceutical equivalence studies data, report and CDP profile shall be submitted.	Firm has submitted Pharmaceutical equivalence and CDP stuies of the product with Sprycel 100mg Tablet (Bristol-Myers Squibb).

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

1152.	The instant case is deleted due to duplication.
1153.	The instant case is deleted due to duplication.
1154.	The instant case is deleted due to duplication.

1155.	**Name, address of Applicant / Importer**	M/s: AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Karachi.
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/149 Address1st Floor, Shafi Court, Merewether Road, Karachi. Address of Godown: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22-02-2028. Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147-3 & L-147/A Verna Industrial Estate, Verna, Goa.

	Name, address of manufacturer(s)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147-3 & L-147/A Verna Industrial Estate, Verna, Goa.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: GVB-MTT-J9RM dated May 24th, 2024
	Details of fee submitted	Rs. 150,000/- dated 14-10-2023 Rs. 150,000/- dated 03-05-2024
	The proposed proprietary name / brand name	**Nilotinib capsule 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Nilotinib as D tartrate ….. 200mg
	Pharmacotherapeutic Group of (API)	Anti-neoplastic agent. Tasigna is indicated for the treatment of: - adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase, - adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available, - paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib
	Reference to Finished product specifications	Manufacturer specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2024/81) valid upto 13-06-2025 issued by Directorate of Food And Drugs Administration, Govt. of Goa. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted Notarized "Letter of Authorization" from M/s Cipla in name of M/s A.j Mirza for the applied product.
EVALUATION OF DATA		
Proposed Pack size		4's
Proposed unit price		As per SRO
The status in reference regulatory authorities		Tasigna capsule Approved by EMA
For generic drugs (me-too status)		Tasigna 200mg capsule of Novartis Pharma (Pakistan) Limited.
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template.

Name, address of drug substance manufacturer		Cipla Ltd Bommasandra, Karnatka, India
Module-III Drug Substance:		Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:		Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence		Firm has submitted pharmaceutical equivalence and CDP report against reference product Tasigna capsule
Analytical method validation/verification of product		Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product		Alu-Alu
Stability study data of drug product, shelf life and storage conditions		Firm has submitted long term stability data of 3 batches for 9 months at 30±2°C, 75±5%RH and 6 months at 40°C±75%RH for three batches.
Decision: Deferred for following: • **Reference Drug Product utilizes Nilotinib Hydrochloride Monohydrate however, Cipla test product is developed with Nilotinib D-Tartrate. Justification shall be submitted in this regard.** • **Long term stability studies data shall be submitted till claimed shelf life.**		
1156.	**Name, address of Applicant / Importer**	M/s: AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Karachi.
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/149 Address: 1st Floor, Shafi Court, Merewether Road, Karachi. Address of Godown: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22-02-2028. Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147-3 & L-147/A Verna Industrial Estate, Verna, Goa.
	Name, address of manufacturer(s)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147-3 & L-147/A Verna Industrial Estate, Verna, Goa.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: 8H1-PJD-8P69 dated May 27th, 2024
	Details of fee submitted	Rs. 150,000/- dated 14-10-2023 Rs. 150,000/- dated 03-05-2024
	The proposed proprietary name / brand name	**Nilotinib capsule 150mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Nilotinib as D tartrate ….. 150mg
	Pharmacotherapeutic Group of (API)	Anti-neoplastic agent. Tasigna is indicated for the treatment of:

		- adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase, - adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available, - paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib
	Reference to Finished product specifications	Manufacturer specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2024/80) valid upto 13-06-2025 issued by Directorate of Food And Drugs Administration, Govt. of Goa. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted Notarized "Letter of Authorization" from M/s Cipla in name of M/s A.j Mirza for the applied product.

EVALUATION OF DATA	
Proposed Pack size	4's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Tasigna capsule Approved by EMA
For generic drugs (me-too status)	Tasigna 150mg capsule of Novartis Pharma (Pakistan) Limited.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Cipla Ltd Bommasandra, Karnatka, India.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalence and CDP report against reference product Tasigna capsule.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Alu-Alu
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 9 months at 30±2°C, 75±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC(XXIV):

- Reference Drug Product utilizes Nilotinib Hydrochloride Monohydrate however, Cipla test product is developed with Nilotinib D-Tartrate. Justification shall be submitted in this regard.
- Long term stability studies data shall be submitted till claimed shelf life.

Decision: Deferred for following: • **Reference Drug Product utilizes Nilotinib Hydrochloride Monohydrate however, Cipla test product is developed with Nilotinib D-Tartrate. Justification shall be submitted in this regard.** • **Long term stability studies data shall be submitted till claimed shelf life.**		
1157.	**Name, address of Applicant / Importer**	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East,On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial zone, Karaj, Iran.
	Name, address of manufacturer(s)	Actero Middle East, On the corner of 8th Golestan , Sarvestan Blvd., Baharestan Industrial zone Karaj Iran.
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: 6H5-5V7-13Q2: 14-05-2024
	Details of fee submitted	PKR 300,000/-: 18-04-2024
	The proposed proprietary name / brand name	**Luvica 140mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Ibrutinib …….140mg
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic, BTK Inhibitor
	Reference to Finished product specifications	In-House specification
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Relevant CoPP not submitted.
	Details of letter of authorization / sole agency agreement	Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement.

EVALUATION OF DATA	
Proposed Pack size	90 Capsules in HDPE container
Proposed unit price	As Per SRO.
The status in reference regulatory authorities	Imbruvica 140mg capsule by M/s Janssen Biotech, USA.
For generic drugs (me-too status)	Not available.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Hetro Labs Limited, Unit-I No.10 I.D.A Gaddapotharam Village, Jinnaram Manadal. Sangareddy District-502319 Telangana, INDIA.

Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and CDP of their product against Innovtor's Imbruvica 140 mg capsule.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	HDPE container
Stability study data of drug product, shelf life and storage conditions	Submit stability studies data of three batches till claimed shelf at long term stability conditions and at accelerated stability conditions for 6 months. Justification shall be submitted for variation in batch sizes of two submitted stability batches.

Evaluation by PEC (XXIV):

Sr. No.	Section	Observations	Reply of the Firm
1.	**1.3**	Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement.	Reply of the firm is still irrelevant as the submitted LOA is still same as the previously submitted one.
2**.**	**1.5.6**	Submitted specifications declared as "In house specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC	Firm has stated that they will follow Innovator's specification, however, fee is not submitted for revision of specifications.
3.	**3.2.P.2.2.1**	Comparative dissolution studies in three dissolution mediums i.e., pH 1.23, pH 4.5 & pH 6.8 shall be submitted since firm has provided CDP data for only one medium i.e., pH 6.8.	Firm has attached a document in which principle states "our drug product Imbuvica capsule is USFDA approved and as per recommendations we have performed CDP study in one medium i.e. pH 6.8,and it is not recommended to perform it in three dissolution mediums".
4.	**3.2.P.8.3**	Submit stability studies data of three batches till claimed shelf at long term stability conditions and at accelerated stability conditions for 6 months. Justification shall be submitted for variation in batch sizes of two submitted stability batches.	The principle has provided us commitment letter as per ICH guideline ICH-Q1A(R2) point 2.1.8, and have committed that they will submit the stability data for third batch and onward stability data for batch C2216. we have asked the principle to provide justification regarding variation in batch sizes, we will submit that as provided by the principal.

Decision: Approved with innovator's specifications subject to submission of fee for revision of specification i.e. 7500/-.
Registration letter shall be issued after the submission of the following data/ documents/clarification.

- **Clarification of name of Market Authorization Holder (abroad).**

• **Submit stability studies data of third batch till claimed shelf at long term stability conditions and at accelerated stability conditions for 6 months.**

Local Manufacture
Routine Cases:

1158.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30594 dated 30-10-2022
	Details of fee submitted	PKR 75,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …10mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Brivaracetam Tablet (USFDA tentatively Approved)
	For generic drugs (me-too status)	Brevatam 10mg tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	Proposed unit price & Pack size	As per SRO

Remarks of Evaluator (XXIV):

Sr No.	Observations	Firm's response
1.	Documents for the procurement of API with approval from DRAP.	**Submitted**
2.	CoA of the drug substance both from drug substance manufacturer and drug product manufacturer with same batch number shall be submitted.	**Submitted**

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1159.	**Deleted due to repetition of case.**

New Section

Firm has been granted new section Dry powder oral suspension (cephalosporin) by the Central Licensing Board in its 252nd meeting held on 15th March, 2017 vide letter No. F. 1-1/95-Lic(Vil-

III) dated 11th April, 2017. As per available record following is the 2nd application by the firm on the basis of new section.

1160.	Name, address of Applicant / Marketing Authorization Holder	Don Valley Pharmaceuticals (Pvt.) Limited, 31-KM Main Ferozepur Road, Lahore.
	Name, address of Manufacturing site.	Don Valley Pharmaceuticals (Pvt.) Limited, 31-KM Main Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID 9MN-SWY-B4A8 25-03-2024
	Details of fee submitted	PKR 30,000/-: 19-03-2024
	The proposed proprietary name / brand name	**Daclocef 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cepradine……250mg
	Pharmacotherapeutic Group of (API)	Antibiotic (Cephalosporin)
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Nicef (Cephradine 250mg/5ml Suspension) MHRA UK Approved).
	For generic drugs (me-too status)	Velocef 250mg/5ml Suspension by M/s gsk Pharma.
	Proposed unit price & Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1161.	**Deleted due to repetition of case.**	

Deferred Cases: -

New DML

1162.	Name, address of Applicant / Marketing Authorization Holder	M/s Al Barakat Pharmaceutical Industries, Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro
	Name, address of Manufacturing site.	M/s Al Barakat Pharmaceutical Industries, Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML granted on 18-10-2023 .
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-7/2017-Lic. dated 18th October, 2023 specifying Liquid Injectable Vial SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID No U38-37A-ZXG4 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- dated 02-12-2023
	The proposed proprietary name / brand name	**Alpara Infusion 1gm/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Paracetamol 1gm
	Pharmacotherapeutic Group of (API)	Antipyretic
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Provas Infusion of M/s Sami
	Name and address of API manufacturer.	M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Provas Infusion of M/s Sami
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan
API Lot No.	23GN6-10094
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	PAR-TB-001	PAR-TB-002	PAR-TB-003
Batch Size	30L	30L	30L
Manufacturing Date	05-2023	05-2023	05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by Additional Director I&E, DRAP Karachi issued on basis of inspection conducted on 7-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Frim has submitted loan letter from M/s Ahson Drug Co. T/1 SITE Tando Adam.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

Sr No.	Observations	Firm's response
1.	Finished product specifications applied in Form 5F are BP Specifications whereas no monograph is available for the applied formulation, furthermore, in testing methods Albarkat Specs. are mentioned, justification shall be submitted in this regard.	Firm has declared it as typing mistake and has submitted finished drug product specifications as Al Barkat specifications.
2.	Drug product analytical method verification studies have not been submitted.	Submitted
3.	Batch size justification shall be submitted against the number of units required to complete the stability studies till claimed shelf life.	Submitted
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

Decision of 335th RB meeting: Deferred for submission of following:

- Compete batch manufacturing record for three stability batches
- Documents confirming procurement of drug substance.

Sr. No.	Observations	Reply of the Firm
1.	Compete batch manufacturing record for three stability batches	Submitted.
1.	Documents confirming procurement of drug substance.	Firm has submitted copy of letter indicating the procurement of drug substance from M/s Ahsons Drug Company, Sindh on loan basis.

Decision: Approved with Manufacturer's Specifications subject to submission of fee for revision of specification i.e. 7500/-.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. : Registration applications of New Section of Human drugs on Form 5-F (Local)

The Central Licensing Board in its 278th meeting held on 10th & 11th December, 2020 has considered and approved the grant of following four additional new sections to M/s Wezen Pharmaceuticals, Plot No. 23 & 24, SI, Industrial Estate, Rawat., under DML No.000882(Formulation), vide letter No. F. 1-30/2014-Lic. dated 30th December, 2020.

Sr. No.	Sections
1.	Tablet (General)
2.	**Capsule (General)**
3.	**Sachet (General)**
4.	Ointment/Creams/Gel (General)

Following 03 applications have been submitted by the firm for registration: -

1163.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26280 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 0292275887
	The proposed proprietary name / brand name	**Riseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril…10mg
	Pharmacotherapeutic Group of (API)	Antidarrheal
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.

	For generic drugs (me-too status)	Hidrasec 10mg Sachet of M/s Abbott Laboratories Pakistan Limited.
	Name and address of API manufacturer.	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Hidrasec 10mg Sachet of M/s Abbott Laboratories Pakistan Limited. Comparative Dissolution Profile: Not performed.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
API Lot No.	2RAC0480622
Description of Pack (Container closure system)	Sachet
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1500 Sachet	1500 Sachet	1500 Sachet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted.

Decision of 335th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr No.	Observations	Firm's response
1.	Renewal status of the DML shall be submitted.	Receiving of renewal application of DML is submitted, dated:28.03.2023. that is in the due time.
2.	Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.	GMP certificate not submitted, however, inspection report conducted on 03.12.2020 & 04.12.2020 is submitted which covers the Capsule (general) section and Sachet section.
3.	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted.	Firm has submitted copy of R & I receiving dated 16.02.2023 of a letter with subject Intimation of Material Obtained (Rececadotril 600gm) as Loan for Stability Studies from M/s Weather Folds Pharmaceuticals on 15.12.2022.

4.	Comparative dissolution not performed for granular powder. Justification shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1164.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26281 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 262247312450
	The proposed proprietary name / brand name	**Riseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril…30mg
	Pharmacotherapeutic Group of (API)	Antidarrheal
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Hidrasec 30mg Sachet of M/s Abbott Laboratories Pakistan Limited.
	Name and address of API manufacturer.	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Hidrasec 30mg Sachet of M/s Abbott Laboratories Pakistan Limited. Comparative Dissolution Profile: Not performed.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.		
API Lot No.	2RAC0480622		
Description of Pack (Container closure system)	Capsules in blister of 16's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1500 Sachet	1500 Sachet	1500 Sachet
Manufacturing Date	01-2023	01-2023	01-2023

Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted in this regard.
- Comparative dissolution not performed for granular powder. Justification shall be submitted.

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr No.	Observations	**Firm's response**
1.	Renewal status of the DML shall be submitted.	Receiving of renewal application of DML is submitted, dated:28.03.2023. that is in the due time.
2.	Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.	GMP certificate not submitted, however, inspection report conducted on 03.12.2020 & 04.12.2020 is submitted which covers the Capsule (general) section and Sachet section.
3.	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted.	Firm has submitted copy of R & I receiving dated 16.02.2023 of a letter with subject Intimation of Material Obtained (Rececadotril 600gm) as Loan for Stability Studies from M/s Weather Folds Pharmaceuticals on 15.12.2022.
4.	Comparative dissolution not performed for granular powder. Justification shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1165.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26282 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 4657522497
	The proposed proprietary name / brand name	**Riseka 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Racecadotril…100mg
	Pharmacotherapeutic Group of (API)	Antidarrheal
	Pharmaceutical form of applied drug	white to almost white powder filled in hard gelatin capsule.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1*16's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Hidrasec 100mg Capsule of M/s Abbott Laboratories Pakistan Limited.
	Name and address of API manufacturer.	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical & equivalence comparative dissolution profile of their product against Hidrasec 100mg Capsules of M/s Abbott Laboratories Pakistan Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Symed Labs Limited Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.		
API Lot No.	2RAC0480622		
Description of Pack (Container closure system)	Sachet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Capsules	1200 Capsules	1200 Capsules
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted in this regard.

Decision of 335th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr No.	Observations	Firm's response
1.	Renewal status of the DML shall be submitted.	Receiving of renewal application of DML is submitted, dated:28.03.2023. that is in the due time.
2.	Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.	GMP certificate not submitted, however, inspection report conducted on 03.12.2020 & 04.12.2020 is submitted which covers the Capsule (general) section and Sachet section.
3.	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted.	Firm has submitted copy of R & I receiving dated 16.02.2023 of a letter with subject Intimation of Material Obtained (Rececadotril 600gm) as Loan for Stability Studies from M/s Weather Folds Pharmaceuticals on 15.12.2022.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

CASES OF EXPORT FACILITATION

Deputy Director (PRV/EFD) vide letter No. F. 1-6/2019-PR-1(EFD) dated 06-10-2023 has informed that M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi., has reached the benchmark of more than 100,000USD during fiscal year 2020-2021 and requested for the priority consideration of the following molecule: -

1166.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi.(DML#000124)

	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Indus Pharma (Pvt.) Ltd. issued on the basis of inspection dated 17-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 21-07-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & details of fee submitted	Dy. No 23857 dated 08-09-2023 PKR 30,000/-: dated 08/08/2023 Slip # 7369179742
	The proposed proprietary name / brand name	Tapentadol 100mg ER Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended-release tablet contains: Tapentadol (as hydrochloride) ……100mg
	Pharmacotherapeutic Group of (API)	Opioid Analgesic
	Pharmaceutical form of applied drug	Film coated, Extended-Release Tablet
	Reference to Finished product specifications	As per innovator's product
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PALEXIA® SR 100 mg Tablet Grünenthal GmbH, Zieglerstrasse 6, 52078, Aachen, Germany.
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	Ami Lifesciences Private Limited. Block No.82/B, ECP Road, AT & Post: Karakhadi 391450, Taluka: Padra, District Vadodara Gujarat, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Tapentadol HCl: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30 °C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Innovator's product Nucynta ER Tablet 100mg.

		Firm has submitted Comparative Dissolution Profile studies against Innovator's product Nucynta ER Tablet 100mg.
	Analytical method validation/verification of product	Firm has submitted Analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Ami Lifesciences Private Limited. Block No.82/B, ECP Road, AT & Post: Karakhadi391450, Taluka: Padra, District Vadodara Gujarat, INDIA.		
API Lot No.	Tapentadol HCl: TPT/50010121		
Description of Pack (Container closure system)	Alu-Alu Blister Strips.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% RH Accelerated: 40°C ± 2°C / 75% RH		
Time Period	Real time: 12 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 12 (Months)		
Batch No.	TR-1/ TPD 100mg ER Tab	TR-2/ TPD 100mg ER Tab	TR-3/ TPD 100mg ER Tab
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	04-2022	04-2022	04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP of the firm (No.22043267) issued by FDCA India. The certificate is valid till 17-04-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice cleared by DRAP Karachi office dated 21-06-2021 specifying import of 2Kg Tapentadol HCl (batch# TPT/50010121).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Remarks of Evaluator PEC (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Routine case
Local Manufacture

1167.	Name, address of Applicant / Marketing Authorization Holder	M/s High-Q Pharmaceuticals, Plots No. B-64 KDA-1, Karsaz road, Karachi.
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plots No. 224 & 225/1, Sector-23, Korangi Industrial Area, Karachi. (DML#000597)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 28254 dated 05-10-2022
	Details of fee submitted	PKR 30,000/-: dated 30/09/2022
	The proposed proprietary name / brand name	**Ongen 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron hydrochloride dihydrate ……4mg
	Pharmacotherapeutic Group of (API)	5HT3 Receptor Antagonist
	Reference to Finished product specifications	Innovator's specifications
EVALUATION OF DATA		
GMP status of the firm		Firm has submitted copy of GMP certificate that was valid till 29-06-2023.
Evidence of approval of manufacturing facility		Firm has submitted copy of letter of grant of section dated 17-09-2021 specifying Liquid Syrup (General) section.
Proposed Pack size		As per SRO
Proposed unit price		As per SRO
The status in reference regulatory authorities		Ondansetron hydrochloride Oral syrup 4mg/5ml of M/s Amneal Pharma (USFDA Approved)
For generic drugs (me-too status)		Onseron Syrup of M/s Indus Pharma.
Name and address of API manufacturer.		CTX Life Sciences Pvt. Ltd., Block No. 251/P, 253 to 255, 256/P,258/P,276/P,277,278/P,279 to 282,283/P, 384/P, GIDC, City Sachin, Dist. Surat, Gujrat State, INDIA.

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Onseron 4mg/5ml Syrup of M/s Indus Pharma.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	ON200004		
Description of Pack (Container closure system)	Amber coloured glass bottle.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	4ONSPD01/2022	4ONSPD02/2022	4ONSPD03/2022
Batch Size	1000ml (20 bottles)	1000ml (20 bottles)	1000ml (20 bottles)
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-02-2022	01-02-2022	01-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No.22063346) of the firm M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 384/P, GIDC, City Sachin, Dist. Surat, Gujrat State, INDIA, issued by FDCA India. The certificate is valid till 29-05-2025.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has not submitted attested copy of invoice for the procurement of API.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (XXIV):

Sr. No.	Observations	Response of the Firm
1.	Proof of API procurement/import and its clearance from the AD (I&E), DRAP, Karachi is not provided.	Firm has informed that they have received 1kg sample of ondansetron from manufacturer (CTX Lafe Sciences) directly through courier and same batch of material is used for trial of Ongene syrup. Firm has submitted copy of airway bill and tracking details as well.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Cases Of Export Facilitation

Deputy Director (PRV/EFD) vide letter No. F. 1-6/2019-PR-1(EFD) dated 28-02-2023 has informed that M/s Searl Company Limited, Karachi, has reached the benchmark of more than 100,000USD during fiscal year 2020-2021 and requested for the priority consideration of the following molecule: -

1168.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28659 dated: 10/10/2022
	Details of fee submitted	PKR 75,000/-, dated 30/09/2022
	The proposed proprietary name / brand name	Obilet 5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Obilet 5mg Tablets Each film coated tablet contains: Obeticholic Acid..... 5mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, bile acids and derivatives
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by UK, with the name of OCALIVA 5mg film-coated tablets
	For generic drugs (me-too status)	Not Available
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022. Valid till 04-08-2024 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Obeticholic Acid: Manufacturer: M/s A.R. Life Sciences Private Limited (Unit II) Plot no. 33, S.V. Co-op. Industrial estate, Jeedimetla, Qutubullapur, Medchal Dist. Hyderabad-Telangana state India-500055
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Relevant information has been submitted including Analytical method validation studies & batch analysis.
	Stability studies	OBETICHOLIC ACID: Stability study conditions: Long term: 5°C ± 3°C for 24 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the reference product that is "Abeticolic 5 mg tablets" by Dyson Research Laboratories (Pvt.) Limited. CDP has been performed against the same the reference product that is "Abeticolic 5 mg tablets" by Dyson Research Laboratories (Pvt.) Limited.
	Analytical method validation/verification of product	Method validation studies have submitted including system suitability, specificity, linearity, accuracy, precision, robustness, and range
STABILITY STUDY DATA		

Manufacturer of API	Obeticholic Acid: Manufacturer: M/s A.R. Life Sciences Private Limited (Unit II) Address: Plot no. 33, S.V. Co-op. Industrial estate, Jeedimetla, Qutubullapur, Medchal Dist. Hyderabad-Telangana state India-500055		
API Lot No.	Obeticholic Acid: CEDC-10(M)/01220		
Description of Pack (Container closure system)	ALU-ALU Blisters in Unit Carton (1 x 10's)		
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21PD-174	21PD-175	21PD-176
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Aug-2021	Aug-2021	Aug-2021
Date of Initiation	Aug-2021	Aug-2021	Aug-2021
No. of Batches	03		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted documents for reference of previous approval.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Obeticholic Acid: GMP Certificate of Manufacturer: AR Life Sciences Pvt Ltd. Valid Till: 19-07-2023
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Obeticholic Acid: Invoice Invoice Number: 9013325130 dated 25.11.2020 Quantity: 0.250 kg
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks OF Evaluator (XXIV):

Sr No.	Observations	Firm's response
1.	Submit valid DML/GMP certificate of drug substance manufacturers issued by relevant regulatory authority of country of origin.	Company has submitted GMP Certificate of Manufacturer i.e. AR Life Sciences Pvt Ltd. Issued by Drugs Control Administration, Telangana, India Valid Till: 29-06-2024
2.	Analytical method verification studies of drug substances shall be submitted from M/s Searle Company Limited.	Submitted.

3.	Submit COA of relevant batch used for preparation for drug product trial batches, from drug substance manufacturer.	Submitted.
4.	Justification shall be submitted for not performing Pharmaceutical Equivalence and CDP studies against the innovator product.	Company has submitted that the innovator product i.e. Ocaliva 5mg tablet is not available in Pakistan, therefore, they have performed pharmaceutical equivalence and CDP studies against the marked brand i.e. Abeticolic 10mg tablet Manufactured by M/s Dyson Pharmaceuticals, (Pvt.) Ltd., Lahore.
5.	Details of the manufacturer of comparator brand shall be submitted, against which Pharmaceutical Equivalence and CDP studies have been performed.	Abeticolic 5mg Tablet Manufactured by: M/s Dyson Pharmaceuticals, (Pvt.) Ltd., Lahore.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1169.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate, Karachi. (DML# 000016)
	Name, address of Manufacturing site.	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28660 dated: 10/10/2022
	Details of fee submitted	PKR 75,000/-, dated 30/09/2022
	The proposed proprietary name / brand name	Obilet 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Obilet 10mg Tablets Each film coated tablet contains: Obeticholic Acid..... 10mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, bile acids and derivatives
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by UK, with the name of OCALIVA 10mg film-coated tablets
	For generic drugs (me-too status)	Not Available
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022.

		Valid till: 04-08-2024 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Obeticholic Acid: Manufacturer: M/s A.R. Life Sciences Private Limited (Unit II) Address: Plot no. 33, Sri Venkateswara Co-op. Indl. Estate, Jeedimetla, Hyderabad, Jeedimetla Quthbullapur Mandal, Medchal-Malkajgiri District. Telangana State, India-500055
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Relevant information has been submitted including Analytical method validation studies & batch analysis.
	Stability studies	OBETICHOLIC ACID: Stability study conditions: Long term: 5°C ± 3°C for 24 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the reference product that is "Abeticolic 10 mg tablets" by Dyson Research Laboratories (Pvt.) Limited. CDP has been performed against the same the reference product that is "Abeticolic 10 mg tablets" by Dyson Research Laboratories (Pvt.) Limited.
	Analytical method validation/verification of product	Method validation studies have submitted including system suitability, specificity, linearity, accuracy, precision, robustness, and range
STABILITY STUDY DATA		
Manufacturer of API	Obeticholic Acid: Manufacturer: M/s A.R. Life Sciences Private Limited (Unit II) Address: Plot no. 33, Sri Venkateswara Co-op. Indl. Estate, Jeedimetla, Hyderabad, Jeedimetla Quthbullapur Mandal, Medchal-Malkajgiri Disttrict. Telangana State, India-500055	

API Lot No.	Obeticholic Acid: CEDC-10(M)/01220		
Description of Pack (Container closure system)	ALU-ALU Blisters in Unit Carton (1 x 10's)		
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21PD-030	21PD-031	21PD-032
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Feb-2021	Feb-2021	Feb-2021
Date of Initiation	March-2021	March-2021	March-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted documents for Reference of Previous Approval
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Obeticholic Acid: GMP Certificate of Manufacturer: AR Life Sciences Pvt Ltd. Valid Till: 19-07-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Obeticholic Acid: Invoice Invoice Number: 9013325130 dated 25.11.2020 Quantity: 0.250 kg Batch: CEDC-10(M)/01220
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator (XXIV):

Sr No.	Observations	Firm's response
1.	Submit valid DML/GMP certificate of drug substance manufacturers issued by relevant regulatory authority of country of origin.	Company has submitted GMP Certificate of Manufacturer i.e. AR Life Sciences Pvt Ltd. Issued by Drugs Control Administration, Telangana, India Valid Till: 29-06-2024
2.	Analytical method verification studies of drug substances shall be submitted from M/s Searle Company Limited.	Submitted.
3.	Submit COA of relevant batch used for preparation for drug product trial batches, from drug substance manufacturer.	Submitted.

4.	Justification shall be submitted for not performing Pharmaceutical Equivalence and CDP studies against the innovator product.	Company has submitted that the innovator product i.e. Ocaliva 10mg tablet is not available in Pakistan, therefore, they have performed pharmaceutical equivalence and CDP studies against the marked brand i.e. Abeticolic 10mg tablet Manufactured by M/s Dyson Pharmaceuticals, (Pvt.) Ltd., Lahore.
5.	Details of the manufacturer of comparator brand shall be submitted, against which Pharmaceutical Equivalence and CDP studies have been performed.	Abeticolic 10mg Tablet Manufactured by: M/s Dyson Pharmaceuticals, (Pvt.) Ltd., Lahore.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Cases Of Export Facilitation

Deputy Director (PRV/EFD) vide letter No. F. 1-6/2019-PR-1(EFD) dated 02-06-2023 has informed that M/s Searl Pakistan Limited, Karachi, has reached the benchmark of more than 100,000USD during fiscal year 2020-2021 and requested for the priority consideration of the following molecules: -

1170.	Name, address of Applicant / Marketing Authorization Holder	M/s Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-02-2022 based on inspection conducted on 08-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-10-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3665 dated 08-02-2023
	Details of fee submitted	PKR 30,000/- Dated 19-12-2022
	The proposed proprietary name / brand name	**Aldomet Tablets 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Methyl Dopa …..... 500mg
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP
	Proposed Pack size	6 x 10’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aldomet 500mg Tablets (USFDA Approved)
	For generic drugs (me-too status)	Aldomet of M/s OBS Pakistan (MSD) (Reg.No. 000312)
	Name and address of API manufacturer.	Zhejiang Chiral Medicine Chemicals Co., Ltd, Nanyang Economy Development Zone, Xiaoshan, Hangzhou, Zhejiang Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP of their product against the reference product Aldomet Tablets 500mg manufactured by Aspen Port Elizabeth (Pty) Ltd, South Africa.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Chiral Medicine Chemicals Co., Ltd, Nanyang Economy Development Zone, Xiaoshan, Hangzhou, Zhejiang Province, China
API Lot No.	MEB-20220115
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3 & 6 (Months)		
Batch No.	091DT02	091DT03	091DT04
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	19-07-2022	19-07-2022	19-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any details.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Certificate of issued by European Directorate for the Quality of Medicines & Healthcare.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted electronic clearance certificate (No. E-317769026941 dated 11-03-2022) specifying 3625 kgs Methyldopa.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1171.	Name, address of Applicant / Marketing Authorization Holder	M/s Searle Pakistan Limited, Plot No.C-14, Manghopir Road, S.I.T.E., Karachi. (DML# 000012)
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, Plot No.C-14, Manghopir Road, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-02-2022 valid till 14-02-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-10-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No., date of submission & Details of fee submitted	Dy. No. 610 dated 06-01-2023 PKR 30,000/- Dated 19-12-2022
	The proposed proprietary name / brand name	**Disyn Tablets 5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin …..... 5mg
	Pharmacotherapeutic Group of (API)	SGLT2 Inhibitors
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	2 x 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Farxiga Tablets (USFDA Approved)
	For generic drugs (me-too status)	Xiga Tablet 5mg of M/s CCL Pharmaceutical (Pvt) Ltd (Reg.No. 090504)
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Dapagliflozin: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP of their product against the test/reference product Farxiga

		Tablets 5mg manufactured by AstraZenica, USA.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, Province -123000, China		
API Lot No.	DG-20201201-D03-DG06-01		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3 & 6 (Months)		
Batch No.	074DT02	074DT03	074DT04
Batch Size	3000 Tablets / 0.338235 Kg	3000 Tablets / 0.338235 Kg	3000 Tablets / 0.338235 Kg
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-08-2021	09-08-2021	09-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. LN210012) inspection dated 21-05-2021 issued by People's Republic of China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 07-05-2021 specifying 400gm of Dapagliflozin Propanediol Monohydrate. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator (XXIV):

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1172.	Name, address of Applicant / Marketing Authorization Holder	M/s Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Name, address of Manufacturing site	M/s Searle Pakistan Limited, C-14, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-02-2022 based on inspection conducted on 08-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-10-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	**Dy. No** 608 dated 06-01-2023
	Details of fee submitted	PKR 30,000/- Dated 19-12-2022
	The proposed proprietary name / brand name	**Disyn Tablets 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin …..... 10mg
	Pharmacotherapeutic Group of (API)	SGLT2 Inhibitors
	Pharmaceutical form of applied drug	Yellow diamond shaped film coated tablet with both sides plain.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	2 x 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Farxiga Tablets (USFDA Approved)
	For generic drugs (me-too status)	Xiga Tablet 10mg of M/s CCL Pharmaceutical (Pvt) Ltd (Reg.No. 090505)
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP of their product against the test/reference product Farxiga Tablets 10mg manufactured by AstraZenica, USA.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, Province -123000, China		
API Lot No.	DG-20201201-D03-DG06-01		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3 & 6 (Months)		
Batch No.	068DT02	068DT03	068DT04
Batch Size	3000 Tablets / 0.6765 Kg	3000 Tablets / 0.6765 Kg	3000 Tablets / 0.6765 Kg
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	16-07-2021	16-07-2021	16-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any details.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. LN210012) inspection dated 21-05-2021 issued by People's Republic of China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 07-05-2021 specifying 400gm of Dapagliflozin

		Propanediol Monohydrate. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Agenda of Evaluator PEC-XXV

Case no. 01 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

1173.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-Ben 200 Granules
	Composition	Each Kg contains: Albendazole…200gm
	Diary No. Date of R& I & fee	Dy.No 22746 dated 11-08-2022 Rs.30,000/- dated 11-08-2022 (slip No. 784208008)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Bendazole Oral Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.117214)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1174.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-Doxy Water Soluble Powder
	Composition	Each Kg contains: Doxycycline HCl…200gm Tylosin tartrate…100gm Colistin Sulphate…50MIU Bromhexine HCl…2gm
	Diary No. Date of R& I & fee	Dy.No 23821 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 2981447450)
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Doximax Powder of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 074019)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1175.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	FCTC Oral Water Soluble Powder
	Composition	Each Kg contains: Chlortetracycline HCl…200gm
	Diary No. Date of R& I & fee	Dy.No 23822 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 10095866)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Tetra Shell 20 Water Soluble Powder of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 075775)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1176.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fagofon 96% Powder
	Composition	Each gram contains: Trichlorfon…960mg
	Diary No. Date of R& I & fee	Dy.No 22749 dated 11-08-2022 Rs.30,000/- dated 10-08-2022 (slip No. 497583244)
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Ectozone-96 Powder of M/s QAS International, Kamoki, District Gujranwala. (Reg. No. 117073)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection

		conducted on 15-04-2022.
	Decision: Approved.	
1177.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-Tet Powder
	Composition	Each Kg contains: Oxytetracycline HCl…30% Florfenicol…30%
	Diary No. Date of R& I & fee	Dy.No 22747 dated 11-08-2022 Rs.30,000/- dated 10-08-2022 (slip No. 28525946889)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Biofoxy 30% Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No.117173)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1178.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	E-Tet Powder
	Composition	Each Kg contains: Oxytetracycline HCl…100gm Erythromycin thiocyanate…150gm
	Diary No. Date of R& I & fee	Dy.No 23826 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 7841241065)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Eryhtro-25 Powder of Attabak Pharmaceuticals, Islamabad (Reg. No. 075716)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1179.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fagofon 98% Powder
	Composition	Each gram contains: Trichlorfon…980mg
	Diary No. Date of R& I & fee	Dy.No 22750 dated 11-08-2022 Rs.30,000/- dated 10-08-2022 (slip No. 8708308253)
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications

	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Ectozone-98 Powder of M/s QAS International, Kamoki, District Gujranwala. (Reg. No.117074)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1180.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	TB Mix Powder
	Composition	Each gram contains: Bromhexine HCl…10mg Tartaric acid…150mg
	Diary No. Date of R& I & fee	Dy.No 22748 dated 11-08-2022 Rs.30,000/- dated 10-08-2022 (slip No. 25613704331)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Broexine Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 117244)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1181.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Neofat Water Soluble Powder
	Composition	Each Kg contains: Neomycin Sulphate…28.59%
	Diary No. Date of R& I & fee	Dy.No 23827 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 51691005684)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Highneo 28.59 % Oral Powder of M/s Acme Pharmaceuticals, Rawat, Islamabad.(Reg. No. 116969)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1182.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Didox Water Soluble Powder

	Composition	Each 1000gm contains: Doxycycline HCl…200gm Tylosin tartrate…100gm Dihydrospectinomycin…40gm Bromhexine HCl …5gm
	Diary No. Date of R& I & fee	Dy.No 23828 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 3663576424)
	Pharmacological Group	Antibacterial, mucolytic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	DS-Majidox Powder of M/s Majestic Pharma, Faisalabad. (Reg. No.118458)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1183.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Leesol Water Soluble Powder
	Composition	Each 100gm contains: Levamisole HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 23829 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 90019640)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Xamin 20% Oral Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad (Reg. No. 101440)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1184.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	E-Neo Powder
	Composition	Each 1000gm contains: Oxytetracycline HCl…200gm Neomycin Sulphate…100gm Erythromycin thiocyanate…100gm
	Diary No. Date of R& I & fee	Dy.No 23823 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 1309528121)
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Neoxeryth Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117146)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1185.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Erynate Powder
	Composition	Each gm contains: Erythromycin thiocyanate…200mg
	Diary No. Date of R& I & fee	Dy.No 23825 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 1728426849)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Erythromytle Oral Powder of M/s Myrtle Pharma, Bin Qasim, Karachi.(Reg. No. 073956)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1186.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Guarox Powder
	Composition	Each Kg contains: Roxithromycin…10gm Tylosin Tartrate…10gm Guaifenesin…17.5gm
	Diary No. Date of R& I & fee	Dy.No 23824 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 59988156)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Roxi-TG Oral Powder of M/s Mallard Pharmaceutical (Pvt) Ltd Multan (Reg. No. 058931)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1187.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.

	Brand Name +Dosage Form + Strength	O-Flox Liquid
	Composition	Each 100ml contains: Ofloxacin…10gm
	Diary No. Date of R& I & fee	Dy.No 23820 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 9951322311)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L; Decontrolled
	Me-too status	Erasol 10 Oral Liquid of M/s Suave Pharmaceuticals Pvt. Ltd., Khurianwala, Faisalabad (Reg. No. 119688)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Liquid General Veterinary section** confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1188.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-Toltra Liquid
	Composition	Each ml contains: Toltrazuril…25mg
	Diary No. Date of R& I & fee	Dy.No 23819 dated 23-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 67672012358)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L; Decontrolled
	Me-too status	Baycox 2.5% Oral Solution of M/s Onesto Enterprises (Pvt) Ltd, Islamabad (Reg. No. 117008)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator	**Oral Liquid General Veterinary section** confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved.	
1189.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Metafos Plus Injection 50ml
	Composition	Each ml contains: Toldimfos Sodium.....200mg Vitamin B12.....0.05mg
	Diary No. Date of R& I & fee	Dy.No 28649 dated 10-10-2022 Rs.30,000/- dated 05-10-2022 (slip No. 11578903932)
	Pharmacological Group	Mineral Supplement
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Toldibar Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118648)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection

		conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1190.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Ryno-10 Injection 50ml
	Composition	Each ml contains: Meloxicam.....10mg
	Diary No. Date of R& I & fee	Dy.No 28650 dated 10-10-2022 Rs.30,000/- dated 05-10-2022 (slip No. 58300773235)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Diclozon 10 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119693)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1191.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Ryno-20 Injection 50ml
	Composition	Each ml contains: Meloxicam.....20mg
	Diary No. Date of R& I & fee	Dy.No 28651 dated 10-10-2022 Rs.30,000/- dated 05-10-2022 (slip No. 951619799387)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Diclozon 20 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119692)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1192.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxazol Plus Drench
	Composition	Each ml contains: Oxfendazole.....22.65mg Triclabendazole.....85mg

	Diary No. Date of R& I & fee	Dy.No 29742 dated 20-10-2022 Rs.30,000/- dated 17-10-2022 (slip No. 3148850625)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml; Decontrolled
	Me-too status	Hawk Vorex Oral Suspension of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat (Reg. No. 118615)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1193.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Vernil-400 Bolus
	Composition	Each bolus contains: Levamisole HCl.....400mg
	Diary No. Date of R& I & fee	Dy.No 29859 dated 21-10-2022 Rs.30,000/- dated 18-10-2022 (slip No. 830338306860)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Famisol 400 Bolus of M/s Farm Aid Group, Haripur (Reg. No. 114878)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1194.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Vernil-1125 Bolus
	Composition	Each bolus contains: Levamisole HCl.....1125mg
	Diary No. Date of R& I & fee	Dy.No 29860 dated 21-10-2022 Rs.30,000/- dated 18-10-2022 (slip No. 636984544)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Famisol 1125 Bolus of M/s Farm Aid Group, Haripur (Reg. No. 114876)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1195.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenzole-750 Bolus

	Composition	Each bolus contains: Fenbendazole.....750mg
	Diary No. Date of R& I & fee	Dy.No 29741 dated 20-10-2022 Rs.30,000/- dated 17-10-2022 (slip No. 782539267459)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Fensel Bolus of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 109970)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1196.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Antil Injection
	Composition	Each ml contains: Pheniramine maleate.....11.35mg
	Diary No. Date of R& I & fee	Dy.No 24495 dated 30-10-2022 Rs.30,000/- dated 24-10-2022 (slip No. 2386595249)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Antil Injection of M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No. 074750)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved.	
1197.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Fosvet Powder
	Composition	Each 100gm contains: Calcium Fosfomycin.....25%
	Diary No. Date of R& I & fee	Dy.No 24497 dated 30-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 4584266477)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	200gm, 1Kg, 5Kg and 40Kg; Decontrolled
	Me-too status	Fosmium Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 118659)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Approved.	

1198.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Fosvet Plus-T Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20% Tylosin Tartrate…5%
	Diary No. Date of R& I & fee	Dy.No 24498 dated 30-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 0365875502)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	200gm, 1Kg, 5Kg and 40Kg; Decontrolled
	Me-too status	Sinfos Oral Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke (Reg. No. 111426)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Approved.	
1199.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Fosomax Oral Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 24496 dated 30-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 59784750)
	Pharmacological Group	Antibacterial with energy complex and booster
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, and 2.5Kg; Decontrolled
	Me-too status	Fosiril Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118610)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1200.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isbucin 10ml Injection

	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 28536 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 2453974920)
	Pharmacological Group	Vitamin Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Butasol Injection of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 106655)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1201.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isbucin 50ml Injection
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 28537 dated 07-10-2022 Rs.30,000/- dated 12-05-2022 (slip No. 5621828023)
	Pharmacological Group	Vitamin Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Butafos Injection of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 109795)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1202.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isbucin 100ml Injection
	Composition	Each ml contains: Butaphosphan…100mg

		Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 28538 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 2759843485)
	Pharmacological Group	Vitamin Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Eagle Catofull Injection of M/s U.M. Enterprises, Karachi. (Reg. No.117300)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1203.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isdoctin 10ml Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 28539 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 467174460)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	V-Mec Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118423)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1204.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isdoctin 50ml Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 28540 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 93556476021)
	Pharmacological Group	Anthelmintic

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Doramax Injection of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 117222)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1205.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isdoctin 100ml Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 28541 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 049727889)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Doravect Injection of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113557)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1206.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isdirine 50ml Injection
	Composition	Each ml contains: Diminazene Aceturate…105mg **Antipyrine**…131mg
	Diary No. Date of R& I & fee	Dy.No 28532 dated 07-10-2022 Rs.30,000/- dated 12-05-2022 (slip No. 0770717913)
	Pharmacological Group	Parasiticide
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Pronifas Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No.080724)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1207.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Novomox-25 Injection
	Composition	Each ml contains: Amoxicillin Trihydrate …250mg (eq. to Amoxicillin Base.....200mg)
	Diary No. Date of R& I & fee	Dy.No 28533 dated 07-10-2022 Rs.30,000/- dated 22-09-2022 (slip No. 38489969)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Amoxizon 20% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119715)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1208.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Islifone C 300ml Injection
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Calcium D Sachharate…1gm Boric Acid…4.33gm Dextrose Anhydrous…20gm
	Diary No. Date of R& I & fee	Dy.No 28534 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 1313290499)
	Pharmacological Group	Nutritional Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	**300ml**; Decontrolled
	Me-too status	Betic Injection of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 097907)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.

	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Confirmation of **relevant manufacturing facility i.e. LVP** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility, i.e. LVP** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1209.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Islifone C 450ml Injection
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Calcium D Sachharate…1gm Boric Acid…4.33gm Dextrose Anhydrous…20gm
	Diary No. Date of R& I & fee	Dy.No 28535 dated 07-10-2022 Rs.30,000/- dated 29-06-2022 (slip No. 0473726729)
	Pharmacological Group	Nutritional Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	450ml; Decontrolled
	Me-too status	Dicalfon-C Injection of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 073912)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary) section** confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Confirmation of **relevant manufacturing facility** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility, i.e. LVP** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1210.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Thiamcol 25 Oral Liquid
	Composition	Each ml contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 26101 dated 14-09-2022 Rs.30,000/- dated 08-09-2022 (slip No. 25474157)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1L and 5L; Decontrolled
	Me-too status	Thiamax Solution of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 118454)
	GMP status	
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed vide letter No.F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
1211.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pridox 75 Water Soluble Powder
	Composition	Each gram contains: Doxycycline as Hyclate…750mg
	Diary No. Date of R& I & fee	Dy.No 29858 dated 21-10-2022 Rs.30,000/- dated 26-09-2022 (slip No. 44275863609)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1Kg; Decontrolled
	Me-too status	**Not available in the applied strength**
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry, calves **Shortcomings:** • The instant formulation in the applied strength is not already registered in Pakistan. The firm has submitted reference of DOXYCYCLINE 75% Kela, 750 mg/g, powder for oral use in drinking water or feed **for pigs** approved in **Belgium**. • latest GMP inspection report conducted within the period of last three years • confirmation of **relevant manufacturing facility** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for following: • **availability of the said formulation approved for poultry and calves in any reference country or PICs member country or ML-4 country.** • **Confirmation of relevant manufacturing facility.** • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications**	
1212.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Rasmite-1% 10ml Injection
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 26235 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 427572612)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119700)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1213.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Rasmite-2% 10ml Injection
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 26236 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 38033527905)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ivozon 2% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119697)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1214.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Sulfabact 10ml Injection
	Composition	Each 100ml contains: Trimethoprim…8gm Sulphadiazine…40gm
	Diary No. Date of R& I & fee	Dy.No 26238 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 00826800)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Triface Injection of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113544)

	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1215.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Sulfabact 50ml Injection
	Composition	Each 100ml contains: Trimethoprim…8gm Sulphadiazine…40gm
	Diary No. Date of R& I & fee	Dy.No 26239 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 41103466539)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Triben Injection of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113556)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1216.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fluximin 10ml Injection
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 26233 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 8248932249)
	Pharmacological Group	Analgesic & Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No.119707)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	

	• **latest GMP inspection report conducted within the period of last three years.**	
1217.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Marboras 20ml Injection
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 26232 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 19524520554)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Reboxin Injection of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 117001)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1218.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Caloras 250ml Injection
	Composition	Each 250ml contains: Calcium Gluconate…50gm Sodium Dimethyl-Aminomethyl Phenyl-Phosphonite…1g. Magnesium Camphosulfonate…2gm Boric Acid…6gm Sorbitol…12.5gm
	Diary No. Date of R& I & fee	Dy.No 26231 dated 16-09-2022 Rs.30,000/- dated 14-09-2021 (slip No. 8302577017)
	Pharmacological Group	Metabolic stimulant & restorative formula
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	**250ml**; Decontrolled
	Me-too status	Calcimax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 088126)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility, i.e. LVP**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility, i.e. LVP**	
1219.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Rasmostin Forte Oral Powder
	Composition	Each 100gm contains: Amoxycillin Trihydrate…50gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 26234 dated 16-09-2022 Rs.30,000/- dated 14-09-2022 (slip No. 3210705680)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Amcostin 50% Water Soluble Powder of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg. No.117103)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	**Oral Dry Powder (Penicillin) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **latest GMP inspection report conducted within the period of last three years.**	
1220.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Sulfabact Oral Suspension
	Composition	Each 100ml Contains: Trimethoprim…8gm Sulphadiazine…40gm
	Diary No. Date of R& I & fee	Dy.No 26237 dated 16-09-2022 Rs.30,000/- dated 14-09-2022 (slip No. 30111831772)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1L, 5L, 10L, 25L; Decontrolled
	Me-too status	Triph Oral Suspension of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118547)
	GMP status	Panel inspection dated 10-03-2021 for renewal of DML and grant of additional sections.
	Remarks of the Evaluator	**Oral Liquid (Antibiotic) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1221.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Nitrox 100ml Injection
	Composition	Each ml contains:

		Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 25499 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 25328018514)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Nitrox Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 117221)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. • The applied formulation is **already registered** for the applicant vide Reg. No. 117221 with brand name Nitrox injection in 100ml pack size.
	Decision: Registration Board disposed of the instant application since same formulation is already registered for the applicant vide Reg. No. 117221 with brand name Nitrox injection in 100ml pack size.	
1222.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Butasol 50ml Injection
	Composition	Each ml contains: Butaphosphan…100mg Vitamin B12…0.05mg
	Diary No. Date of R& I & fee	Dy.No 25502 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 1424263322)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Butafos Injection of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 109795)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1223.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Afonac 50ml Injection
	Composition	Each ml contains: Aceclofenac as Sodium…25mg
	Diary No. Date of R& I & fee	Dy.No 25492 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 0312703616)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	I-Acefenac Injection of M/s International Pharma Labs. Lahore. (Reg. No.094437)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.

	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.	
1224.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Adifon 50ml Injection
	Composition	Each ml contains: Sodium Selenite…0.5mg Vitamin E…70mg Vitamin B12…0.1mg Vitamin B1…20mg Adenosine 5-Monophosphate…5mg
	Diary No. Date of R& I & fee	Dy.No 25505 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 439693782)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	I-Vitamin Super Injection of M/s International Pharma Labs. Lahore. (Reg. No. 062066)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1225.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Doramax 50ml Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 25500 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 5983301554)
	Pharmacological Group	Ecto- and Endoparasiticide
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Doramax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 117222)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. The applied formulation is **already registered** for the applicant vide Reg. No. 117222 with brand name Doramax injection in 50ml pack size.
	Decision: Registration Board disposed of the instant application since same formulation is already registered for the applicant vide Reg. No. 117222 with brand name Doramax injection in 50ml pack size.	
1226.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur

	Brand Name +Dosage Form + Strength	Torvit 50ml Injection
	Composition	Each ml contains: Toldimfos Sodium…200mg Vitamin B12…0.05mg
	Diary No. Date of R& I & fee	Dy.No 25494 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 11902714425)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Bio-Fos Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad.(Reg. No. 117177)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1227.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Iverlon 50ml Injection
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 25495 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 28541044503)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Evo-C Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117311)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1228.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Iverlon 100ml Injection
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 25501 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 8011143145)

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Mecloxon-110 Injection of M/s Farm Aid Group, Haripur (Reg. No.117259)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1229.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Clozectin 50ml Injection
	Composition	Each ml contains: Closantel as Sodium…125mg Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 25497 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 951992258)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Clomec Injection of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 062112)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1230.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Clozectin 100ml Injection
	Composition	Each ml contains: Closantel as Sodium…125mg Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 25496 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 54080992)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Clomec Injection of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 062112)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021

		concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1231.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Sulfolex 100ml Injection
	Composition	Each ml contains: Sulphadimidine Sodium…333.3mg
	Diary No. Date of R& I & fee	Dy.No 25498 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 26800715936)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Sulfafiz Injection of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore. (Reg. No.081339)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1232.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Kelsen 100ml Injection
	Composition	Each 100ml contains: Calcium Gluconate…38.71gm Boric Acid…7.29gm Calcium Hydroxide…1.32gm Magnesium Chloride…6.50gm
	Diary No. Date of R& I & fee	Dy.No 25503 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 2554408539)
	Pharmacological Group	Calcium and magnesium supplement
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Bovical Injection of M/s Pharmaceutical Management Services Karachi. (Reg. No. 021268)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	

1233.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Mytro 50ml Injection
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 25493 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 391190726)
	Pharmacological Group	Anti-muscrinic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Atrobar Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117369)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1234.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Biodyl 50ml Injection
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…0.100gm Potassium Aspartate Semihydrate…1gm Magnesium Aspartate Tetrahydrate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 25504 dated 08-09-2022 Rs.30,000/- dated 26-08-2022 (slip No. 813973755)
	Pharmacological Group	Antistress
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Actibol Injection (**100ml**) of M/ Selmore Pharmaceuticals (Pvt) Limited, Lahore 112155)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1235.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Ami-Vicom 50ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.4mg L-Cysteine HCl...3.2mg L-Glutamine...3.2mg Glycine...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg

		L-Lysine HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Tryptophan...0.86mg L-Phenylalanine...5mg L-Valine...3.60mg Thiamine HCl...4mg Riboflavin Sodium Phosphate...0.17mg Pyridoxine HCl...0.34mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg
	Diary No. Date of R& I & fee	Dy.No 27635 dated 29-09-2022 Rs.30,000/- dated 20-09-2022 (slip No. 08642351029)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **latest GMP inspection report conducted within the period of last three years indicating the required testing facility.**	
1236.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Ami-Vicom 100ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.4mg L-Cysteine HCl...3.2mg L-Glutamine...3.2mg Glycine...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg L-Lysine HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Tryptophan...0.86mg L-Phenylalanine...5mg L-Valine...3.60mg Thiamine HCl...4mg Riboflavin Sodium Phosphate...0.17mg Pyridoxine HCl...0.34mg Ascorbic Acid...4mg

		Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg
	Diary No. Date of R& I & fee	Dy.No 27634 dated 29-09-2022 Rs.30,000/- dated 21-09-2022 (slip No. 47615553041)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **latest GMP inspection report conducted within the period of last three years indicating the required testing facility**	
1237.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Ami-Vicom 250ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.4mg L-Cysteine HCl...3.2mg L-Glutamine...3.2mg Glycine...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg L-Lysine HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Tryptophan...0.86mg L-Phenylalanine...5mg L-Valine...3.60mg Thiamine HCl...4mg Riboflavin Sodium Phosphate...0.17mg Pyridoxine HCl...0.34mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg
	Diary No. Date of R& I & fee	Dy.No 27633 dated 29-09-2022 Rs.30,000/- dated 21-09-2022 (slip No. 8908234636)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	**250ml**; Decontrolled

	Me-too status	Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility, i.e. LVP** • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **latest GMP inspection report conducted within the period of last three years indicating the required testing facility**	
1238.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur.
	Brand Name +Dosage Form + Strength	Duphalyte Injection 500ml
	Composition	Each ml contains: Vitamin B1(HCl)...0.10mg Vitamin B2 (as Sodium phosphate) ...0.04mg Vitamin B6 (HCl)...0.10mg Vitamin B12...0.05µg Nicotinamide...1.50mg D-Panthenol...0.05mg Calcium Chloride Hexahydrate...0.23mg Magnesium Sulphate 7H2O...0.29mg Potassium Chloride...0.20mg Anhydrous Dextrose...45.46mg L-Arginine HCl...0.025mg L-Cysteine HCl Monohydrate...0.01mg Monosodium Glutamate...0.04mg L-Hystidine HCl Monohydrate...0.01mg L-Isoleucine...0.01mg L-Leucine...0.04mg L-Lysine HCl...0.03mg L-Methionine...0.01mg DL-Phenylalanine...0.03mg L-Threonine...0.02mg DL-Tryptophan...0.01mg DL-Valine...0.05mg
	Diary No. Date of R& I & fee	Dy.No 27637 dated 29-09-2022 Rs.30,000/- dated 20-09-2022 (slip No. 7737259920)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied combination**
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:**

		• Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility i.e LVP** • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **latest GMP inspection report conducted within the period of last three years indicating the required testing facility**	
1239.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Prolium WSP
	Composition	Each 100gm contains: Amprolium HCl…50gm
	Diary No. Date of R& I & fee	Dy.No 27636 dated 29-09-2022 Rs.30,000/- dated 20-09-2022 (slip No. 2111174438)
	Pharmacological Group	Anti-protozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	Amprozone-50 Water Soluble Powder of M/s QAS International, Kamoki, District Gujranwala (Reg. No. 117078)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Approved. Firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1240.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Dicox Forte Water Soluble Powder
	Composition	Each gram contains: Amprolium as HCl…175mg Sulphaquinoxaline as Sodium…175mg Vitamin A (Retinol concentrate powder) …15000IU Vitamin K3 (Menadiol Sodium phosphate)…5mg
	Diary No. Date of R& I & fee	Dy.No 27638 dated 29-09-2022 Rs.30,000/- dated 20-09-2022 (slip No. 048234188)
	Pharmacological Group	Anti-protozoal and vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Dicox Forte Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 049529)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018. **Shortcomings:**

		Stability of instant formulation along with master formula
	Decision: Deferred for submission of stability of instant formulation along with master formula and latest GMP inspection report conducted within the period of last three years indicating the required testing facility	
1241.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Alvenax-152 Bolus
	Composition	Each bolus contains: Albendazole…152mg
	Diary No. Date of R& I & fee	Dy.No 27159 dated 26-09-2022 Rs.30,000/- dated 22-09-2022 (slip No. 0424605649)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20's and 50's; Decontrolled
	Me-too status	Marozole-152 Bolus of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 112292)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1242.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ampro-90 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…900gm
	Diary No. Date of R& I & fee	Dy.No 33422 dated 21-11-2022 Rs.30,000/- dated 17-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, and 2500gm; Decontrolled
	Me-too status	Mprokam-90 Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119737)
	GMP status	cGMP certificate dated 08-12-2021 based on inspection conducted on 07-12-2021.
	Remarks of the Evaluator	Approval of **Dry Powder Suspension (General) (veterinary)** section confirmed vide letter No.F. 1-31/2010-Lic dated 25-11-2016
	Decision: Approved.	
1243.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vita-C Powder
	Composition	Each 1000gm contains: **Paracetamol**…200gm **Vitamin C**…50gm Potassium Carbonate…125gm Sodium Bicarbonate…125gm Vitamin E…12.50gm
	Diary No. Date of R& I & fee	Dy.No 33425 dated 21-11-2022 Rs.30,000/- dated 17-11-2022 (slip No. 660207857)
	Pharmacological Group	Antipyretic/Antioxidants

	Type of Form	Form-5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	C-Rox Para Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112366)
	GMP status	cGMP certificate dated 08-12-2021 based on inspection conducted on 07-12-2021.
	Remarks of the Evaluator	Approval of **Dry Powder Suspension (General) (veterinary)** section confirmed vide letter No.F. 1-31/2010-Lic dated 25-11-2016
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1244.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-ADEK Oral Liquid
	Composition	Each ml contains: Vitamin A…10,000IU Vitamin D3…2000IU Vitamin E…4mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 32804 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 726606503)
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml, 5L, 10L, 25L; Decontrolled
	Me-too status	ADEKAL LIQUID of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 118627)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1245.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Dex Gold Oral Liquid
	Composition	Each 1000ml contains: Levamisole HCl…75gm Triclabendazole…120gm
	Diary No. Date of R& I & fee	Dy.No 32806 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 084638152787)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Triclev Drench 120mg/75mg of M/s Lucky Core Industries Limited, Lahore (Reg. No. 116816)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1246.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-ADEK Powder
	Composition	Each Kg contains: Vitamin A…20 MIU Vitamin D3…2 MIU Vitamin E…6000mg Vitamin K3…5000mg
	Diary No. Date of R& I & fee	Dy.No 32805 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 796305973666)
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 200gm, 250gm, 500gm, 1Kg, 5Kg; Decontrolled
	Me-too status	Radek Oral Powder of M/s Ras Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 096832)
	GMP status	
	Remarks of the Evaluator	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1247.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Dex SC Oral Liquid
	Composition	Each 1000ml contains: Triclabendazole…50gm Cobalt Sulphate…1.67gm Sodium Selenite…0.35gm
	Diary No. Date of R& I & fee	Dy.No 32808 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 19814027944)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Endomall SC Oral Drench of M/s Mallard Pharmaceutical (Pvt) Ltd Multan (Reg. No. 058921)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1248.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Dex Plus Oral Liquid
	Composition	Each 1000ml contains: Levamisole HCl…37.50gm Triclabendazole…50gm Cobalt Sulphate…1.67gm Sodium Selenite…0.35gm

	Diary No. Date of R& I & fee	Dy.No 32807 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 246158195507)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Triclorise-CS Oral Drench of M/s Biorise Pharmaceuticals, Multan.(Reg. No. 111190)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1249.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Faciozan 1.5% Oral Liquid
	Composition	Each 1000ml contains: Rafoxanide…15gm Levamisole HCl…15gm
	Diary No. Date of R& I & fee	Dy.No 32809 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 05425667)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	**Not provided**
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **latest GMP inspection report conducted within period of last three years** • **evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1250.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Alba-Raf Oral Liquid
	Composition	Each 1000ml contains: Rafoxanide…22.70gm Albendazole…25gm
	Diary No. Date of R& I & fee	Dy.No 32810 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 620024566719)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	**Not provided**
	GMP status	

	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **latest GMP inspection report conducted within period of last three years** • **evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1251.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Boxer Plus Oral Suspension
	Composition	Each 1000ml contains: Oxfendazole…22.65gm Oxyclozanide…62.5gm Cobalt Sulphate…1.67gm Sodium Selenite…0.50gm
	Diary No. Date of R& I & fee	Dy.No 32803 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 0555617802)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Sodox Oral Drench of M/s Athan Pharmaceuticals, Hattar. (Reg. No. 115033)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1252.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cenazide Gold Oral Suspension
	Composition	Each 1000ml contains: Levamisole HCl…30gm Oxyclozanide…60gm Cobalt Sulphate…3.34gm Sodium Selenite…1gm
	Diary No. Date of R& I & fee	Dy.No 32802 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 924113659)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Helmex Gold Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 057005)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1253.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Bro N Oral Liquid
	Composition	Each 1000ml contains: Bromhexine HCl…100gm Eucalyptus Oil…100gm Menthol…200gm Cinnnamon Oil…60gm Thymol…200gm Betaine HCl…100gm Sorbitol…100gm
	Diary No. Date of R& I & fee	Dy.No 32801 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 6234333463)
	Pharmacological Group	Antibacterial with Natural oil
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	**Not provided**
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **latest GMP inspection report conducted within period of last three years** • **evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1254.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Vitacena-E Plus Oral Liquid
	Composition	Each 1000ml contains: Vitamin E…100mg Selenium as Sodium Selenite…0.1mg Vitamin C…80mg Betaine HCl…100mg Eucalyptus Oil…150mg Mint Oil…50mg Cinnamon Oil…50mg Sodium Chloride…25mg Calcium Gluconate…20mg Potassium Chloride…15mg Dextrose…220mg
	Diary No. Date of R& I & fee	Dy. No 32800 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 4497347284)
	Pharmacological Group	Bronchodilator with Natural oil
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	**Not provided**

	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **latest GMP inspection report conducted within period of last three years** • **evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1255.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Rovimec 250ml Injection
	Composition	Each ml contains: Ivermectin…10.5mg
	Diary No. Date of R& I & fee	Dy. No 32489 dated 11-11-2022 Rs.30,000/- dated 14-10-2022 (slip No. 4764497978)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	**250ml**; Decontrolled
	Me-too status	I-Mectin Injection of M/s International Pharma Labs., Lahore. (Reg. No. 063618)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility** • Latest GMP inspection report conducted within period of last three years
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility, i.e. LVP** • **Latest GMP inspection report conducted within period of last three years.**	
1256.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Rovimec 100ml Injection
	Composition	Each ml contains: Ivermectin…10.5mg
	Diary No. Date of R& I & fee	Dy.No 32488 dated 11-11-2022 Rs.30,000/- dated 13-10-2022 (slip No. 963198781)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	I-Mectin Injection of M/s International Pharma Labs., Lahore. (Reg. No. 063618)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:**

		Latest GMP inspection report conducted within period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1257.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Nitrox 10ml Injection
	Composition	Each ml contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 32487 dated 11-11-2022 Rs.30,000/- dated 14-10-2022 (slip No. 2386307904)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1258.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Doramax 100ml Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 32486 dated 11-11-2022 Rs.30,000/- dated 14-10-2022 (slip No. 88483992543)
	Pharmacological Group	Ecto- and Endoparasiticide
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Doravect Injection of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113557)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1259.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Pamivet-3 Injection 100ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin E Acetate…20mg Vitamin D3…40,000 IU
	Diary No. Date of R& I & fee	Dy.No 32485 dated 11-11-2022 Rs.30,000/- dated 14-10-2022 (slip No. 2782723513)
	Pharmacological Group	Vitamins
	Type of Form	Form 5

	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aderiq Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117371)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1260.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, Industrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Flutic 10ml Injection
	Composition	Each ml contains: Flunixin as Meglumin…50mg
	Diary No. Date of R& I & fee	Dy.No 23741 dated 22-08-2022 Rs.30,000/- dated 22-08-2022 (slip No. 0657336982)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119707)
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator	**Liquid Injectable Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1261.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Durafer 10ml injection
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 21652 dated 01-08-2022 Rs.30,000/- dated 25-07-2022 (slip No. 3430855182)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Furovetz Injection 50mg of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102017)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1262.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Flofenic 3% Injection 100ml
	Composition	Each ml contains:

		Florfenicol…30mg
	Diary No. Date of R& I & fee	Dy.No 30599 dated 30-10-2022 Rs.30,000/- dated 25-10-2022 (slip No. 84350419259)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Prem Fenicol Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111318)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1263.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adenocyn Injection 10ml
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…0.10gm Potassium Aspartate Semihydrate…1gm Magnesium Aspartate Tetrahydrate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 34281 dated 28-11-2022 Rs.30,000/- dated 16-11-2022 (slip No. 6390093164)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Actibol Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 117322)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1264.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adenocyn Injection 20ml
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…0.10gm Potassium Aspartate Semihydrate…1gm Magnesium Aspartate Tetrahydrate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 34280 dated 28-11-2022 Rs.30,000/- dated 16-11-2022 (slip No. 5503734343)
	Pharmacological Group	Micro nutrients

	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Biosal Injection **(30ml, 50ml, 100ml, 250ml, 300ml, 400ml** and **450ml)** of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1265.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adenocyn Injection 50ml
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…0.10gm Potassium Aspartate Semihydrate…1gm Magnesium Aspartate Tetrahydrate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 34501 dated 29-11-2022 Rs.30,000/- dated 16-11-2022 (slip No. 1599756290)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Biosal Injection **(30ml, 50ml, 100ml, 250ml, 300ml, 400ml** and **450ml)** of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1266.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adenocyn Injection 100ml
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…0.10gm Potassium Aspartate Semihydrate…1gm Magnesium Aspartate Tetrahydrate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 35145 dated 05-12-2022 Rs.30,000/- dated 16-11-2022 (slip No. 99205008397)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Biosal Injection **(30ml, 50ml, 100ml, 250ml, 300ml, 400ml** and **450ml)** of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1267.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cyclosta Spray
	Composition	Each ml contains: Chlortetracycline HCl…15.2mg
	Diary No. Date of R& I & fee	Dy.No 33629 dated 22-11-2022 Rs.30,000/- dated 17-11-2022 (slip No. 7354165296)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	211ml, 325ml; Decontrolled
	Me-too status	Biochlor Aerosol Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088094)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Aerosol General (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1268.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Prednicord-D Injection
	Composition	Each ml contains: **Prednisolone as Acetate**…7.5mg **Dexamethasone as Sodium Phosphate**…2.5mg
	Diary No. Date of R& I & fee	Dy.No 35841 dated 09-12-2022 Rs.30,000/- dated 01-12-2022 (slip No. 4525286176)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	AM-Dpred Injection of M/s International Pharma Labs. Lahore. (Reg. No. 099037)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	**Liquid Injectable (Veterinary) Section** confirmed vide panel inspection report based on inspection conducted on 15-01-2020 for grant of GMP certificate. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O.

		496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1269.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Vetafenac Injection
	Composition	Each ml contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Dy.No 35844 dated 09-12-2022 Rs.30,000/- dated 01-12-2022 (slip No. 2264972882)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Diclozon 7.5 Injection of M/s International Pharma Labs. Lahore. (Reg. No. 119696)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	**Liquid Injectable (Veterinary) Section** confirmed vide panel inspection report based on inspection conducted on 15-01-2020 for grant of GMP certificate.
	Decision: Approved.	
1270.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Fev-O-Nil Injection
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 35845 dated 09-12-2022 Rs.30,000/- dated 01-12-2022 (slip No. 533395342523)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Aceclovetz Injection of M/s Vetz Pharmaceuticals (Pvt) Ltd., Kotri Sindh. (Reg. No. 088160)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	**Liquid Injectable (Veterinary) Section** confirmed vide panel inspection report based on inspection conducted on 15-01-2020 for grant of GMP certificate. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety and efficacy parameters. **The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.**	

1271.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Excefur Injection
	Composition	Each ml contains: Ceftiofur HCl eq. to Ceftiofur…50mg
	Diary No. Date of R& I & fee	Dy.No 35843 dated 09-12-2022 Rs.30,000/- dated 01-12-2022 (slip No. 681207037907)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Redycef RTU Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 115076)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of relevant manufacturing facility, i.e. **Dry Powder injectable (cephalosporin) Veterinary** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for submission of following: • **Confirmation of relevant manufacturing facility, i.e. Dry Powder injectable (cephalosporin) Veterinary** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
1272.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Nilvet Plus Suspension
	Composition	Each 100ml contains: Levamisole HCl…1.5gm Oxyclozanide…3gm Cobalt Sulphate…0.382gm
	Diary No. Date of R& I & fee	Dy.No 35842 dated 09-12-2022 Rs.30,000/- dated 01-12-2022 (slip No. 84794220696)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	150ml; Decontrolled
	Me-too status	Oxzmisole Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 117206)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	**Oral liquid Veterinary (General)** confirmed vide letter No. F.2-44/84-Lic (vol-IV) dated 20-09-2021 **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1273.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Revo Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 39624 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 84688258138)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No.119707)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1274.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Revo Injection 20ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 39625 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 6755465116)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	20ml,: Decontrolled
	Me-too status	Alivios Solution for Injection of M/s Prix Pharmaceutica, Lahore. (Reg. No. 084842)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1275.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Revo Injection 50ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 39622 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 53172565)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119708)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1276.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Revo Injection 100ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 39623 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 197148263508)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Fumin 5% Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117362)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1277.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	OTC Forte LA Injection 50ml
	Composition	Each ml contains: Oxytetracycline …300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 39615 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 301169911)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg. No. 114809)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1278.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Amivit Injection 50ml
	Composition	Each ml contains: L-Arginine HCl…1.44mg L-Cysteine HCl…3.20mg L-Glutamine…3.20mg Glycine…3.20mg L-Histidine…1.32mg L-Isoleucine…3.6mg L-Leucine HCl…4.28mg L-Lysine HCl…5.44mg L-Methionine…3.20mg L-Threonine…3.20mg L-Tryptophan…0.86mg L-Valine…3.60mg Vitamin B1...4mg Riboflavin Sodium Phosphate...0.17mg Vitamin B6...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg

		Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg L-Phenylalnine...5mg
	Diary No. Date of R& I & fee	Dy.No 39616 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 840758836478)
	Pharmacological Group	Vitamin/ Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Aminovital Injection **(50ml, 100ml)** of M/s Star Labs Lahore. (Reg. No. 023491)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1279.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Amivit Injection 100ml
	Composition	Each ml contains: L-Arginine HCl…1.44mg L-Cysteine HCl…3.20mg L-Glutamine…3.20mg Glycine…3.20mg L-Histidine…1.32mg L-Isoleucine…3.6mg L-Leucine HCl…4.28mg L-Lysine HCl…5.44mg L-Methionine…3.20mg L-Threonine…3.20mg L-Tryptophan…0.86mg L-Valine…3.60mg Vitamin B1...4mg Riboflavin Sodium Phosphate...0.17mg Vitamin B6...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg L-Phenylalnine...5mg
	Diary No. Date of R& I & fee	Dy.No 39618 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 2151718815)
	Pharmacological Group	Vitamin/ Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Aminovital Injection (**50ml, 100ml**) of M/s Star Labs Lahore. (Reg. No. 023491)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1280.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Amivit Injection 250ml
	Composition	Each ml contains: L-Arginine HCl…1.44mg L-Cysteine HCl…3.20mg L-Glutamine…3.20mg Glycine…3.20mg L-Histidine…1.32mg L-Isoleucine…3.6mg L-Leucine HCl…4.28mg L-Lysine HCl…5.44mg L-Methionine…3.20mg L-Threonine…3.20mg L-Tryptophan…0.86mg L-Valine…3.60mg Vitamin B1...4mg Riboflavin Sodium Phosphate...0.17mg Vitamin B6...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg L-Phenylalnine...5mg
	Diary No. Date of R& I & fee	Dy.No 39620 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 22074538613)
	Pharmacological Group	Vitamin/ Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	250ml,: Decontrolled
	Me-too status	Aminovital Injection **(50ml, 100ml)** of M/s Star Labs Lahore. (Reg. No. 023491)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
1281.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Incramilk Powder
	Composition	Each 1000gram contains: Calcium…155gm Phosphorous…135gm Magnesium…55gm

		Sodium…45gm Iron…1gm Zinc…3gm Manganese…2gm Copper…0.6gm Cobalt…0.01gm Iodine…0.04gm
	Diary No. Date of R& I & fee	Dy.No 39619 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 77171996805)
	Pharmacological Group	Minerals
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	L.S. Minerals Powder of M/s Nawan Labs Karachi (Reg. No. 021306)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit revised label claim with complete salt form along with the relevant fee before issuance of registration letter.	
1282.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Gold Mineral Powder
	Composition	Each Kg contains: Vitamin A…0.8gm Vitamin D3…0.16gm Vitamin E…0.38gm Vitamin B1…1gm Vitamin B2…1.25gm Vitamin B12...0.001gm Vitamin B3...6.25gm Copper Sulphate...0.25gm Magnesium Sulphate...25gm Calcium Chloride...0.023gm Zinc Sulphate...2.17gm Manganese Sulphate...10gm Potassium Iodide...0.5gm Sodium Selenite...0.01gm Dibasic Calcium Phosphate...150gm Sodium Chloride...120gm Vitamin B6...4gm
	Diary No. Date of R& I & fee	Dy.No 39617 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 6515204091)
	Pharmacological Group	Electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Min Rold Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109284)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1283.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Scour-X Oral Suspension
	Composition	Each ml contains: Sulphadimidine…35mg Sulphadiazine…36mg Streptomycin Sulphate…7.6mg Neomycin Sulphate…1.8mg Sodium Chloride…11.33mg Calcium Gluconate…2.2mg Magnesium Sulphate…0.6mg Potassium Chloride…3.6mg Kaolin…103.33mg Pectin…7.1mg Glycine…20.9mg
	Diary No. Date of R& I & fee	Dy.No 39621 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 55927542038)
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L and 2.5L: Decontrolled
	Me-too status	Neodiaral Oral Suspension of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat. (Reg. No. 118616)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1284.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Pro Scour-X Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.500mg Sulphadimidine…28.400mg Neomycin Sulphate…1.800mg Hyoscine Methylbromide…0.040mg Kaolin…103.300mg Pectin…7.100mg Vitamin B1…0.150mg Vitamin B2…0.220mg Vitamin B6…0.150mg Vitamin K3…4mg
	Diary No. Date of R& I & fee	Dy.No 39626 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 8414312692)
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L and 2.5L: Decontrolled
	Me-too status	Rexin Oral Suspension of M/s Evergreen Pharmaceuticals,

		Lahore. (Reg. No. 118400)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1285.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	GTC-350 50ml Injection
	Composition	Each 100ml contains: Gentamycin Sulphate…5gm Tylosin Tartrate…10gm Colisitin Sulphate…20MIU
	Diary No. Date of R& I & fee	Dy. No 33418 dated 21-11-2022 Rs.30,000/- dated 18-11-2022 (slip No. 94397268496)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Combigent Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 117217)
	GMP status	panel inspection conducted on 14-06-2022 for grant of cGMP certificate concluded fair level of GMP compliance.
	Remarks of the Evaluator	**Injectable Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 14-06-2022 for grant of cGMP certificate. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1286.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	GTC-350 100ml Injection
	Composition	Each 100ml contains: Gentamycin Sulphate…5gm Tylosin Tartrate…10gm Colisitin Sulphate…20MIU
	Diary No. Date of R& I & fee	Dy. No 33419 dated 21-11-2022 Rs.30,000/- dated 18-11-2022 (slip No. 15455938)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Combigent Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088086)
	GMP status	panel inspection conducted on 14-06-2022 for grant of cGMP certificate concluded fair level of GMP compliance.
	Remarks of the Evaluator	**Injectable Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection

		report conducted on 14-06-2022 for grant of cGMP certificate. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1287.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Biomax Paste
	Composition	Each 100gm contains: Ivermectin…1.87gm Praziquantel…14.03gm
	Diary No. Date of R& I & fee	Dy. No 28648 dated 10-10-2022 Rs.30,000/- dated 30-09-2022 (slip No. 84088937)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, 30gm, 40gm, 50gm, 100gm: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • The instant formulation is not already registered in Pakistan. The firm has submitted reference of Equimax paste sold/registered in **South Africa**. • Confirmation of **relevant manufacturing facility.**
	Decision: Deferred for following: • **availability of the said formulation in any reference country or PICs member country or ML-4 country.** • **Confirmation of relevant manufacturing facility.**	
1288.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Biomectin Oral Paste
	Composition	Each 100gm contains: Ivermectin…1.87gm
	Diary No. Date of R& I & fee	Dy. No 28647 dated 10-10-2022 Rs.30,000/- dated 30-09-2022 (slip No. 7025086734)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, 30gm, 40gm, 50gm, 100gm: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**

		• approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries
	Decision: Deferred for following: • **availability of the said formulation in any reference country or PICs member country or ML-4 country.** • **Confirmation of relevant manufacturing facility.**	
1289.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd., Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Hawk Macrofos Oral Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Soidum Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy. No 28936 dated 12-10-2022 Rs.30,000/- dated 20-09-2022 (slip No. 0466450200)
	Pharmacological Group	Antibiotic/Minerals/Carbohydrate
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Fosiril Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd. Multan. (Reg. No. 118610)
	GMP status	Panel inspection conducted on 19-11-2020 for renewal of DML.
	Remarks of the Evaluator	**Veterinary Oral Powder (Antibiotic)** section confirmed vide letter No. F. 1-31/2011-Lic (M-235) dated 03-07-2013. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1290.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Enro Comb Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…50mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy. No 30349 dated 26-10-2022 Rs.30,000/- dated 25-10-2022 (slip No. 83951237)
	Pharmacological Group	Antibacterial/ Coccidial/ bronchodilator
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 250ml, 500ml, 1L, 2.5L, 5L, 10L, 25L: Decontrolled
	Me-too status	Eriroxn Oral Solution of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 111492)
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of

		which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) **Liquid (Veterinary) (General)**
	Remarks of the Evaluator	
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1291.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Renomide Injection 50ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 30997 dated 01-11-2022 Rs.30,000/- dated 26-10-2022 (slip No. 87381037078)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Frusicon Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049685)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1292.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Renomide Injection 100ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 30996 dated 01-11-2022 Rs.30,000/- dated 26-10-2022 (slip No. 6591615308)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Frusicon Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049685)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1293.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Marflox 10 Injection 20ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 30998 dated 01-11-2022 Rs.30,000/- dated 26-10-2022 (slip No. 685344663341)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Reboxin Injection of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 117001)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1294.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Marflox 10 Injection 50ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 31000 dated 01-11-2022 Rs.30,000/- dated 26-10-2022 (slip No. 3217891726)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Marboxin 100 Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 117121)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1295.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Marflox 10 Injection 100ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 30999 dated 01-11-2022 Rs.30,000/- dated 26-10-2022 (slip No. 842613129)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Marbosyva Solution for Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 109963)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1296.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Calcio 250ml Injection
	Composition	Each 250ml contains: Calcium Gluconate ….....50gm Sodium Dimethyl Aminomethyl Phenyl phosphinite… .....1gm Magnesium Camphosulphonate….....2gm Boric Acid….....6gm Sorbitol….....12.50gm
	Diary No. Date of R& I & fee	Dy.No 36727 dated 16-12-2022 Rs.30,000/- dated 29-11-2022 (slip No. 169414165388)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Calcimax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 088126)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic(vol-) dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • Confirmation of **relevant manufacturing facility i.e LVP**
	Decision: Deferred for following: • **latest GMP inspection report conducted within the period of last three years** • **Confirmation of relevant manufacturing facility i.e LVP**	
1297.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Calcio 500ml Injection
	Composition	Each 250ml contains: Calcium Gluconate ….....50gm Sodium Dimethyl Aminomethyl Phenyl phosphinite… .....1gm Magnesium Camphosulphonate….....2gm Boric Acid….....6gm

		Sorbitol….....12.50gm
	Diary No. Date of R& I & fee	Dy.No 36726 dated 16-12-2022 Rs.30,000/- dated 29-11-2022 (slip No. 9093421636)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500ml: Decontrolled
	Me-too status	Calcio PH Injectable Solution of M/s Prix Pharmaceutical Lahore (Reg. No. 018843)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic(vol-) dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • Confirmation of **relevant manufacturing facility i.e LVP**
	Decision: Deferred for following: • **latest GMP inspection report conducted within the period of last three years** • **Confirmation of relevant manufacturing facility i.e LVP**	
1298.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Lyso-Care Powder
	Composition	Each Kg contains: Lysozyme…22% Vitamin E 50SD…0.5%
	Diary No. Date of R& I & fee	Dy.No 38210 dated 28-12-2022 Rs.30,000/- dated 23-12-2022 (slip No.675854203)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1Kg; Decontrolled
	Me-too status	Hylise Water Soluble Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112256)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 **Shortcomings:** • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Approved. The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm before issuance of registration letter.	
1299.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Tylen 10% Premix Powder
	Composition	Each Kg contains: Tylosin Phospahte…100gm
	Diary No. Date of R& I & fee	Dy.No 38209 dated 28-12-2022 Rs.30,000/- dated 23-12-2022 (slip No.7284470182)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1Kg, 5Kg, 20Kg; Decontrolled
	Me-too status	Avilosin 10 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 118657)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 **Shortcomings:** • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm and pre-approval correction in label claim in line with reference product.
	Decision: Approved. The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm and pre-approval correction in label claim in line with reference product.	
1300.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	K-Fos Oral Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Soidum Phosphate…15gm Magnesium Sulphate…20gm
	Diary No. Date of R& I & fee	Dy.No 3659 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.5779710596)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	20gm, 50gm, 100gm, 200gm, 250gm, 500gm, 1000gm, 5Kg, 25Kg; Decontrolled
	Me-too status	Fosforox Oral Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 111291)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1301.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Tribect Plus Oral W/S Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg

		Neomycin Sulphate…150mg Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 3660 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.6379535594)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5Kg; Decontrolled
	Me-too status	Floxy-N Mak Water Soluble Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119741)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1302.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Policol-Forte Oral Powder
	Composition	Each gram contains: Colistin Sulphate…60MIU
	Diary No. Date of R& I & fee	Dy.No 3661 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.055781942)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 5Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The submitted reference of generic product "Grand Colistin Oral Powder" of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 106754) is of different strength (i.e 6MIU/gram) than applied.
	Decision: Deferred for evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1303.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Flustat-100 Powder

	Composition	Each Kg contains: Amantadine HCl…0.1Kg
	Diary No. Date of R& I & fee	Dy.No 3656 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.517895046)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5Kg; Decontrolled
	Me-too status	Krypdine 100 Oral Powder of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113425)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1304.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Lincovet 4.4% Oral Powder
	Composition	Each Gram Contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 3657 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.533812504158)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	500gm, 1000gm, 2.5Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Lincoresis Oral Powder of M/s Medhouse Pharmaceuticals (Pvt) Ltd, Gujrat (Reg. No. 114789)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1305.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	TDC-Forte Oral W/S Powder

	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Colistin Sulphate…1000 MIU Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 3658 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 0532649437)
	Pharmacological Group	Antibacterial, mucolytic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Xinmak Water Soluble Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119731)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1306.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Enkotin Plus Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…20gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy.No 4375 dated 15-02-2023 Rs.30,000/- dated 15-02-2023 (slip No. 741640658352)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100ml, 250ml, 500ml, 900ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Enrokam C-20 Oral Solution of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119751)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Liquid (General) Veterinary (Revised)** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1307.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Score-XP Oral Suspension
	Composition	Each 100ml contains: Sulphadiazine…3.550gm Sulphadimidine…2.840gm Neomycin Sulphate…0.180gm Hyoscine Methylbromide…0.004gm Pectin…0.710gm Kaolin…10.330gm Vitamin B1…0.0150gm Vitamin B2…0.022gm
	Diary No. Date of R& I & fee	Dy.No 3655 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 67462912279)
	Pharmacological Group	Antibacterial, anti toxin, anti spasmodic and vitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Scourzon Oral Suspension of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No.119727)
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator	**Oral Liquid (General) Veterinary (Revised)** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1308.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T.G.C 50 Injection 10ml
	Composition	Each 10ml contains: Tylosin Tartrate…1gm Gentamycin Sulphate…0.5gm Colistin Sulphate…5MIU
	Diary No. Date of R& I & fee	Dy.No 3924 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 32792911164)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.

	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1309.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T.G.C 50 Injection 50ml
	Composition	Each 50ml contains: Tylosin Tartrate…5gm Gentamycin Sulphate…2.5gm Colistin Sulphate…25MIU
	Diary No. Date of R& I & fee	Dy.No 3925 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 1286376881)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 • The firm shall submit fee Rs. 7500/- for pre-approval change/correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1310.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fento Injection 20ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 3920 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 280841152826)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	20ml; Decontrolled

	Me-too status	Catoprofen Injection of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No.101472)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1311.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fento Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 3921 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 355336486)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Catoprofen Injection of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No.101473)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1312.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Wimmex Injection 10ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 3922 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 2645761842)
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ivozon 2% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119697)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1313.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Wimmex Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 3923 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 98822983)

	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ivozon 2% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119699)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1314.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ivermex Injection 250ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 3912 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 58864762246)
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Dectiver Injection (10ml, 50ml, 100ml, 500ml) of M/s Azm Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 019035)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
1315.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Flunimit Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 3916 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 0755626991)
	Pharmacological Group	NSAIDS
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No.119707)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

	Decision: Approved. The firm shall submit following before issuance of registration letter: • **fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
1316.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Flunimit Injection 20ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 3917 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 4157885290)
	Pharmacological Group	NSAIDS
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Fluxim-5% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109942)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
1317.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Wimflue Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine…83mg
	Diary No. Date of R& I & fee	Dy.No 3915 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 031337877)
	Pharmacological Group	NSAIDS
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Flunix Hans 8.3 Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg. No.114837)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1318.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Gelox-20 Injection 50ml
	Composition	Each ml contains:

		Gentamycin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 3911 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 05466349140)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Gantasin-20% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.112222)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within period of last three years.**	
1319.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Loxitar Injection 100ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 3909 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 24819751)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Diclozon 10 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119694)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1320.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Bupacon 5% Injection 50ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 3910 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 438673379861)
	Pharmacological Group	Second generation hydroxynaptaquinone
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Bupex Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118637)

	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **latest GMP inspection report conducted within the period of last three years**	
1321.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxtronil 34% Injection 10ml
	Composition	Each ml contains: Nitroxinil…340mg
	Diary No. Date of R& I & fee	Dy.No 3918 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 259624085363)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1322.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxtronil 34% Injection 50ml
	Composition	Each ml contains: Nitroxinil…340mg
	Diary No. Date of R& I & fee	Dy.No 3919 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 340428795066)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106698)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1323.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.

	Brand Name +Dosage Form + Strength	Loxiwim Injection 100ml
	Composition	Each ml contains: Meloxicam…20mg
	Diary No. Date of R& I & fee	Dy.No 3913 dated 10-02-2023 Rs.30,000/- dated 07-02-2023 (slip No. 57359302542)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Meloxter-20 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 109921)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
1324.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Cyanowim 1000mcg Injection 10ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 3914 dated 10-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 601666352)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Cyanocob 1000 Injection of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No.074021)
	GMP status	cGMP certificate dated 09-12-2019 based on inspection conducted on 08-11-2019.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014 **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **latest GMP inspection report conducted within the period of last three years**	
1325.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Spamolin-E Oral Powder
	Composition	Each gram contains: Amoxicillin as Trihydrate…200mg Lincomycin as HCl…88mg Spectinomycin as HCl…88mg Vitamin E Acetate…30mg
	Diary No. Date of R& I & fee	Dy.No 3529 dated 07-02-2023 Rs.30,000/- dated 30-01-2023 (slip No. 0503162455)

	Pharmacological Group	Antibiotics with vitamin E as an antioxidant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg & 5Kg; Decontrolled
	Me-too status	Saple Sove E Oral Powder of M/s Suave Pharmaceuticals Pvt. Ltd., Faisalabad (Reg. No.116854)
	GMP status	Last GMP inspection is conducted on **03-06-2021** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **oral powder (Penicillin) section** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for submission of following before issuance of registration letter: • **Confirmation of oral powder (Penicillin) section** • **indication and target species** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
1326.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Magnet Injection 100ml
	Composition	Each ml contains: Flunixin Meglumine…83mg
	Diary No. Date of R& I & fee	Dy.No 4030 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 35123666)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Fumin 8.3% Injection of M/s Farm Aid Group, Haripur.(Reg. No. 117365)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1327.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Magnet Injection 50ml
	Composition	Each ml contains: Flunixin Meglumine…83mg
	Diary No. Date of R& I & fee	Dy.No 4027 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 42183373309)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Fumin 8.3% Injection of M/s Farm Aid Group, Haripur.(Reg. No. 117364)

	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1328.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Magnet Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine…83mg
	Diary No. Date of R& I & fee	Dy.No 4035 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 2964763598)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Fumin 8.3% Injection of M/s Farm Aid Group, Haripur.(Reg. No. 117363)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1329.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Vita ADEK Injection 50ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin E Acetate…20mg Vitamin D3…40,000 IU
	Diary No. Date of R& I & fee	Dy.No 4019 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 69144484929)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Pamivet-3 Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 101466)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1330.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Etro Pin Injection 50ml
	Composition	Each ml contains:

		Atropine Sulphate…10mg
	Diary No. Date of R& I & fee	Dy.No 4020 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 61079707882)
	Pharmacological Group	Antimusacrinic agent
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Trupine Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 043582)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1331.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Pro 20 Injection 50ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 4028 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 5283286195)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Enroflox 20 Injection of M/s Attabak Pharmaceutical Industries, Islamabad. (Reg. No. 118589)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1332.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Pro 20 Injection 100ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 4029 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 9894682074)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Penroxacin Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 118649)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.

	Decision: Approved.	
1333.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Marbo 10 Injection 20ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 4026 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 605528950168)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	20ml,: Decontrolled
	Me-too status	Reboxin Injection of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 117001)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1334.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Le Spectin 150 Injection 50ml
	Composition	Each ml contains: Lincomycin HCl eq. to Lincomycin…50mg Spectinomycin HCl eq. to Spectinomycin…100mg
	Diary No. Date of R& I & fee	Dy.No 4032 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 928685413684)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Vetz Linco Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 117210)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1335.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Iver Zental Injection 50ml
	Composition	Each 100ml contains: Ivermectin…1gm Closental…12.5gm
	Diary No. Date of R& I & fee	Dy.No 4033 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 98767553304)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Clomec Injection of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 062112)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1336.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	LSB 129 Injection 50ml
	Composition	Each ml contains: Lincomycin as HCl…40mg Spectinomycin as HCl…80mg Alcohol Benzyl…9mg
	Diary No. Date of R& I & fee	Dy.No 4012 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 18245426)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	LSA Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 063724)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1337.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Oxy Ket Injection 50ml
	Composition	Each ml contains: Oxytetracycline…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 4017 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 799416121208)
	Pharmacological Group	Antibacterial & NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Pro Cycline Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

1338.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Oxy Ket Injection 100ml
	Composition	Each ml contains: Oxytetracycline…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 4013 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 215688653102)
	Pharmacological Group	Antibacterial & NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Pro Cycline Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111329)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1339.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Flor 30 Injection 50ml
	Composition	Each 100ml contains: Florfenicol…30gm
	Diary No. Date of R& I & fee	Dy.No 4023 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 77352917802)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Resflo Injection of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 118566)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1340.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Myphos Injection 100ml
	Composition	Each ml contains: Sodium Acid Phosphate…400mg
	Diary No. Date of R& I & fee	Dy.No 4024 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 0390108345)
	Pharmacological Group	Laxative
	Type of Form	Form 5
	Finished product Specifications	BP specifications

	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Vetzphos Injection of M/s Vetz Pharmaceutical (Pvt) Ltd., Kotri Sindh. (Reg. No. 103963)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, Horses, sheep, goat, dogs, cats, camels **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1341.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Tonosal Injection 50ml
	Composition	Each ml contains: Tonophasphan…100mg Vitamin B12…20mcg
	Diary No. Date of R& I & fee	Dy.No 4031 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 9745696359)
	Pharmacological Group	Vitamin/Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Toposal Injection of M/s Tarobina Corp Lahore (Reg. No.032219)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1342.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Fostel DS Injection 50ml
	Composition	Each ml contains: Toldimfos Sodium…200mg Vitamin B12…0.05mg
	Diary No. Date of R& I & fee	Dy.No 4018 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 8776229418)
	Pharmacological Group	Vitamin/Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Cynofos Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 118598)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	

1343.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Fostel Forte Injection 50ml
	Composition	Each ml contains: Toldimfos Sodium Trihydrate (tonophophan)…124.4mg Vitamin B12…50µg
	Diary No. Date of R& I & fee	Dy.No 4015 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 691914756119)
	Pharmacological Group	Vitamin/Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	New Dechaphosphan Injection **(100ml)** of M/s Atzan Pharmaceuticals, Sargodha (Reg. No. 039972)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1344.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ADE Injection 50ml
	Composition	Each ml contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 4016 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 3573073972)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Adeka Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1345.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Multivit Injection 100ml
	Composition	Each ml contains: Vitamin A…50,000 IU Vitamin D3…25000 IU Vitamin E (acetate)…4mg Vitamin B1…2.5mg Vitamin B2 as Sodium Phosphate…2mg

		Vitamin B6…1.25mg Vitamin B12…30µg Vitamin C…2mg Nicotinamide…12.5mg Dexpanthenol…3mg
	Diary No. Date of R& I & fee	Dy.No 4022 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 14305555257)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Pri- Becovit Injection IM of M/s Prix Pharmaceutica, Lahore. (Reg. No. 099073)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1346.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ami Top Injection 50ml
	Composition	Each ml contains: Dextrose (Glucose)...50mg Calcium Chloride...2mg Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate...7.5mg L-Histidine HCl...0.02mg DL-Methionine...0.525mg L-Tryptophan...0.175mg L-Cystine HCl...0.02mg L-Isoleucine...0.525mg L-Threonine...0.35mg L-Arginine HCl...1.425mg L-Phenylalanine...0.35mg L-Valine...0.525mg L-Lysine HCl...0.525mg L-Leucine...0.6mg Monosodium Glutamate...0.08mg Riboflavin...0.05mg D-Pantothenol...0.1mg Pyridoxine HCl...0.1mg Nicotinamide...3mg Thiamine HCl...0.1mg
	Diary No. Date of R& I & fee	Dy.No 4034 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 282965256)
	Pharmacological Group	Vitamin/Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Aminovital High Injection (**100ml, 250ml)** of M/s Atzan Pharmaceuticals Multan (Reg. No. 020083)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1347.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Cyno DS Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 4014 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 096115048784)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119706)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1348.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Cyno Forte Injection 100ml
	Composition	Each 2ml contains: Cyanocobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No 4025 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 4468735317)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Amvit-250 Injection of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 109912)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1349.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Cyno Sal Injection 50ml
	Composition	Each 100ml contains: Cyanocobalamin…0.05gm Sodium Selenite…100mg Adenosine Triphosphate Tetrasodium Dihydrate Salt…0.100gm

		Potassium Aspartate …1gm Magnesium Aspartate…1.5gm
	Diary No. Date of R& I & fee	Dy.No 4021 dated 13-02-2023 Rs.30,000/- dated 10-02-2023 (slip No. 17657863860)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Biowin Injection of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. (Reg. No. 118451)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1350.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Stin Water Soluble Powder
	Composition	Each 100gram contains: Enrofloxacin…20gm Colistin Sulphate…45MIU
	Diary No. Date of R& I & fee	Dy.No 4036 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 48820139)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	25gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Floxa 20/45 Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 117359)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1351.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Vitagen Super Powder
	Composition	Each 100gm contains: Vitamin A…2,000,000 IU Vitamin D3…400,000 IU Vitamin E…160 IU Vitamin K…900mg Vitamin B1…125mg Vitamin B2…2000mg Vitamin B6…600mg Vitamin B12…3000mcg Vitamin C…1000mg Folic Acid…200mg Nicotinamide…10,000mg Calcium Pantothenate…3000mg
	Diary No. Date of R& I & fee	Dy.No 5677 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 4572877458)

	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vital-P Powder of M/s A & K Pharmaceuticals, Faisalabad (Reg. No. 031567)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1352.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Danocin Oral Powder
	Composition	Each 100gm Contains: Danofloxacin Mesylate…10gm
	Diary No. Date of R& I & fee	Dy.No 5671 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 30428452752)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	KP-Dano 10% Oral Powder of M/s Krypton Pharma (Pvt) Ltd., Faisalabad (Reg. No. 109223)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for confirmation of relevant manufacturing facility and fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
1353.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Cyno-12 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 1541 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 23642022608)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	20ml, 100ml,: Decontrolled
	Me-too status	Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:**

		• Clarification regarding demanded pack size since both 20ml & 100ml is mentioned on Form 5 while 100ml is mentioned on fee challan. Same formulation in 100ml pack is already applied by brand name Cyno Forte Injection 100ml vide Dy.No 4025 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 4468735317) approved in instant meeting.
	Decision: Deferred for submission of clarification regarding demanded pack size since both 20ml & 100ml is mentioned on Form 5 while 100ml is mentioned on fee challan. Same formulation in 100ml pack is already applied by brand name Cyno Forte Injection 100ml vide Dy.No 4025 dated 13-02-2023 Rs.30,000/- dated 13-02-2023 (slip No. 4468735317) approved in instant meeting.	
1354.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Linco 200 Injection 100ml
	Composition	Each ml contains: Spiramycin Adipate…125mg Lincomycin HCl…75mg
	Diary No. Date of R& I & fee	Dy.No 1546 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 0055028311)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Sinco Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 080138)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter	
1355.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Mine Injection 50ml
	Composition	Each ml contains: Mepyramine Maleate…50mg
	Diary No. Date of R& I & fee	Dy.No 1727 dated 18-01-2023 Rs.30,000/- dated 18-01-2023 (slip No. 4784139899)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Meprax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112258)
	GMP status	GMP certificate dated 31-08-2022 based on inspection

		conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1356.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ceclofen 25 Injection 50ml
	Composition	Each ml contains: Aceclofenac as Sodium…25mg
	Diary No. Date of R& I & fee	Dy.No 1552 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 70387653178)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Aklonac Injection of M/s Manhattan Pharma, Karachi. (Reg. No. 106765)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. **The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.**	
1357.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ceclofen 25 Injection 20ml
	Composition	Each ml contains: Aceclofenac as Sodium…25mg
	Diary No. Date of R& I & fee	Dy.No 1551 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 7589797933)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml,: Decontrolled
	Me-too status	Aceclovetz Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 088160)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:**

		• The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. **The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.**	
1358.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Trivit Injection 50ml
	Composition	Each ml contains: DL-Acetylmethionine…200mg Cyanocobalamin…0.2mg L-Carnitine HCl 61.3mg eq. to L-Carnitine…50mg Alpha-Tocopherol Acetate 32.9mg eq. to Alpha-Tocopherol…30mg
	Diary No. Date of R& I & fee	Dy.No 1549 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 35024429155)
	Pharmacological Group	Vitamin & Amino acids
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Sterivit Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 109968)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. Firm shall submit Finished Product Specifications before issuance of registration letter.	
1359.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Trivit Injection 100ml
	Composition	Each ml contains: DL-Acetylmethionine…200mg Cyanocobalamin…0.2mg L-Carnitine HCl 61.3mg eq. to L-Carnitine…50mg Alpha-Tocopherol Acetate 32.9mg eq. to Alpha-Tocopherol…30mg
	Diary No. Date of R& I & fee	Dy.No 1550 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 86427355452)
	Pharmacological Group	Vitamin & Amino acids
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Sterivit Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 095650)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. Firm shall submit Finished Product Specifications before issuance of registration letter.	
1360.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Fasfo-100 Injection 50ml
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…50mcg Taurine…37.3mg Nicotinamide…23mg DL-Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 1728 dated 18-01-2023 Rs.30,000/- dated 18-01-2023 (slip No. 21162292)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Hilfos Injection of M/s Hilton Pharma Pvt Ltd., Karachi. (Reg. No.116939)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1361.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Fasfo-100 Injection 100ml
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…50mcg Taurine…37.3mg Nicotinamide…23mg DL-Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 1547 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 37636317)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Hilfos Injection of M/s Hilton Pharma Pvt Ltd., Karachi. (Reg. No. 116940)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	

1362.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Diuretic Injection 50ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 1548 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 7539962587)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Furason Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 112251)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1363.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ADE Forte Injection 50ml
	Composition	Each 100ml contains: Vitamin A…5,000,000 IU Vitamin D3…2500,000 IU Vitamin E…2000 IU Vitamin B1(Thiamine)…0.2gm Vitamin B3(Nicotinamide)…0.06gm Vitamin B6(Pyridoxine)…0.06gm Vitamin B12(cyanocobalamin)…0.4mg
	Diary No. Date of R& I & fee	Dy.No 1542 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 133035596)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	ADE B-Complex Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046662)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1364.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Carb 120 Injection 10ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg

	Diary No. Date of R& I & fee	Dy.No. 1729 dated 18-01-2023 Rs.30,000/- dated 18-01-2023 (slip No. 536860292854)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Bioimido Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118602)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1365.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Vita Menz Injection 100ml
	Composition	Each ml contains: Vitamin A (Retinyl Palmitate) …80,000 IU Vitamin D3 (Cholecalciferol)…40,000 IU Vitamin E (Alpha tocopherol acetate) …20mg Vitamin B1…2.5mg Vitamin B6…1.25mg Vitamin B12…30mcg
	Diary No. Date of R& I & fee	Dy.No. 1545 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 40227607964)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Vitaject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049646)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1366.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Diro Nill Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate...33.33mg Streptomycin Sulphate…33.33mg Sulphaguanidine...333.33mg

		Kaolin...333.33mg Pectin...33.33mg Bismuth Subnitrate…166.66mg Vitamin A Acetate…2.291mg
	Diary No. Date of R& I & fee	Dy.No 1543 dated 17-01-2023 Rs.30,000/- dated 17-01-2023 (slip No. 56524485671)
	Pharmacological Group	Anti-bacterial, anti-diarrheal, vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	12gm, 125gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Anty-Dyrold Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109133)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
1367.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Gest Powder
	Composition	Each 100gram contains: Propionic Acid Calcium…25gm Propionic Acid Sodium…40gm Acetanilide…15gm Magnesium Oxide…12.5gm Iron II Sulphate…40mg Zinc Sulphate...10mg Magnesium Sulphate…20mg Copper Sulphate…45mg Cobalt Sulphate…40mg Sodium Chloride…2gm Sodium Molybdate…10mg
	Diary No. Date of R& I & fee	Dy.No 1544 dated 17-01-2023 Rs.30,000/- dated 16-01-2023 (slip No. 80157471981)
	Pharmacological Group	Minerals
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Optimust Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109141)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	

1368.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Neogen Oral Powder
	Composition	Each gram contains: Neomycin Sulphate 720mg eq. to Neomycin base…500mg
	Diary No. Date of R& I & fee	Dy.No 5672 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 241811520328)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Neom-72 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118506)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
1369.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	DMG Booster Oral Powder
	Composition	Each Kg contains: Vitamin A…2,000,000 IU Vitamin D3…400,000 IU Vitamin E…160 IU Vitamin K…900mg Vitamin B1…125mg Vitamin B2…2000mg Vitamin B6…600mg Vitamin B12…3000mg Vitamin C…1000mg Folic Acid…200mg Nicotinic Acid…10,000mg Calcium Pantothenate…3000mg L-Lysine...50,000mg DL-Methionine...30,000mg
	Diary No. Date of R& I & fee	Dy.No 5674 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 941626168)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg: Decontrolled
	Me-too status	Kerry Vit Amino Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 031480) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.

	Remarks of the Evaluator	The submitted reference to generic product is of different strength than applied. **Shortcomings:** • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility.** • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1370.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Trisulf Granules
	Composition	Each 100gram contains: Trimethoprim…4.62gm Sulphaquinoxaline…15.02gm
	Diary No. Date of R& I & fee	Dy.No 5675 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 444031460913)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility.** • **Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1371.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Sulftrim-NPB Oral Solution
	Composition	Each ml contains: Norfloxacin…50mg Sulphamethoxypyridazine…50mg Trimethoprim…10mg **Phenylbutazone**…12mg Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 5673 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 145491093)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Anti Crd/B Oral Solution of M/s Rajupt Enterprises Karachi (Reg. No. 018434)

	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision: Deferred for submission of following: • **Confirmation of relevant manufacturing facility** • **Target species**	
1372.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Anti-Scour Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.50mg Sulphadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine Methylbromide…0.040mg Kaolin…103.30mg Pectin…7.10mg Vitamin B1…0.150mg Vitamin B2…0.220mg
	Diary No. Date of R& I & fee	Dy.No 5676 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 29311067)
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 2L, 2.5L: Decontrolled
	Me-too status	Baarex Oral Suspension of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118551)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
1373.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adevit Injection 10ml
	Composition	Each ml contains: Vitamin A (Retinyl Palmitate) …80,000 IU Vitamin D3 (Cholecalciferol)…40,000 IU Vitamin E (DL- Alpha tocopherol acetate) …20mg Vitamin B1…2.5mg Vitamin B6…1.25mg Vitamin B12…30mcg
	Diary No. Date of R& I & fee	Dy.No 36 dated 02-01-2023 Rs.30,000/- dated 28-12-2022 (slip No. 9478407330)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Vitaject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049646)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide

		panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1374.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adevit Injection 50ml
	Composition	Each ml contains: Vitamin A (Retinyl Palmitate) …80,000 IU Vitamin D3 (Cholecalciferol)…40,000 IU Vitamin E (DL- Alpha tocopherol acetate) …20mg Vitamin B1…2.5mg Vitamin B6…1.25mg Vitamin B12…30mcg
	Diary No. Date of R& I & fee	Dy.No 837 dated 10-01-2023 Rs.30,000/- dated 06-01-2023 (slip No. 25275679)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Vitaject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049646)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1375.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Adevit Injection 100ml
	Composition	Each ml contains: Vitamin A (Retinyl Palmitate) …80,000 IU Vitamin D3 (Cholecalciferol)…40,000 IU Vitamin E (DL- Alpha tocopherol acetate) …20mg Vitamin B1…2.5mg Vitamin B6…1.25mg Vitamin B12…30mcg
	Diary No. Date of R& I & fee	Dy.No 838 dated 10-01-2023 Rs.30,000/- dated 06-01-2023 (slip No. 91744501870)
	Pharmacological Group	Micro nutrients
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Vitaject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049646)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	

1376.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxynic Drench
	Composition	Each ml contains: Oxyclozanide…94mg Oxfendazole…34mg Selenium as Sodium Selenite…0.50mg Cobalt as Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 2101 dated 23-01-2023 Rs.30,000/- dated 20-01-2023 (slip No. 21745074123)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Combiox Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 057004)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility** • **latest GMP inspection report conducted within period of last three years.**	
1377.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	E-Quin 25mg/ml Suspension for Injection 50ml
	Composition	Each ml contains: Cefquinome (as sulphate)…25mg
	Diary No. Date of R& I & fee	Dy.No 2251 dated 24-01-2023 Rs.30,000/- dated 16-01-2023 (slip No. 09829648105)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Cefanome Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 114796)
	GMP status	Last GMP inspection is conducted on **03-06-2021** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
1378.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dolocam Forte Injection 50ml
	Composition	Each ml contains:

		Meloxicam…20mg
	Diary No. Date of R& I & fee	Dy.No 1963 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 1483183848)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Diclozon 20 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119692)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1379.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dolocam Forte Injection 100ml
	Composition	Each ml contains: Meloxicam…20mg
	Diary No. Date of R& I & fee	Dy.No 1964 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 5647958271)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Meloxter-20 Injection of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 109921)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years.	
1380.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri Fenac Injection 50ml
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 1965 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 492542084)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Aklonac Injection of M/s Manhattan Pharma, Karachi. (Reg. No. 106765)
	GMP status	

	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. **The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.**	
1381.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri Fenac Injection 100ml
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 1966 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 75932010432)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Aklonac Injection **(50ml)** of M/s Manhattan Pharma, Karachi. (Reg. No. 106765)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.	
1382.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri Calphos Injection 300ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Calcium D-Saccharate…1gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 1968 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 05589039180)
	Pharmacological Group	Restorative

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	300ml: Decontrolled
	Me-too status	Dicalfon-C Injection (300ml, 450ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility, i.e LVP** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility, i.e LVP** • **Latest GMP inspection report conducted within the period of last three years.**	
1383.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri Calphos Injection 450ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Calcium D-Saccharate…1gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 1962 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 84129257537)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	450ml: Decontrolled
	Me-too status	Dicalfon-C Injection (300ml, 450ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility, i.e LVP** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility, i.e LVP** • **Latest GMP inspection report conducted within the period of last three years.**	
1384.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Tet WSP
	Composition	Each gram contains: Tilmicosin Phosphate…100mg Enrofloxacin…100mg Trimethoprim…50mg

	Diary No. Date of R& I & fee	Dy.No 4531 dated 16-02-2023 Rs.30,000/- dated 02-02-2023 (slip No. 4209843409)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 1000gm: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility** • The instant formulation is not already registered in Pakistan. The firm has submitted reference of Trimicosin-M sold/registered in **Germany**, which could not be confirmed. • approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility** • **approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries** • **Latest GMP inspection report conducted within the period of last three years.**	
1385.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Pri-Tet Oral Liquid
	Composition	Each ml contains: Tilmicosin Phosphate…50mg Enrofloxacin…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 4530 dated 16-02-2023 Rs.30,000/- dated 02-02-2023(slip No. 914233285)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 1000ml, 5L; Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • The instant formulation is not already registered in Pakistan. The firm has submitted reference of Trimicosin-M sold/registered in **Germany**, which could not be confirmed. • approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries** • **Latest GMP inspection report conducted within the period of last three years.**	

1386.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Prazi-Q Oral Liquid
	Composition	Each ml contains: Praziquantel…25mg
	Diary No. Date of R& I & fee	Dy.No 4529 dated 16-02-2023 Rs.30,000/- dated 02-02-2023 (slip No. 86067026)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 1000ml: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • The instant formulation is not already registered in Pakistan. The firm has submitted reference of Detenase oral suspension sold/registered in **Italy**, which could not be confirmed. • approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries** • **Latest GMP inspection report conducted within the period of last three years.**	
1387.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Metaprim 48 Oral Suspension
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine sodium…400mg
	Diary No. Date of R& I & fee	Dy.No 1967 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 73764646626)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 1000ml: Decontrolled
	Me-too status	Triph oral suspension of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118547)
	GMP status	
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **fee Rs. 30,000/- for correction in label claim in line with reference product and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	

1388.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Levec 3.15% Injection
	Composition	Each ml contains: Ivermectin…31.5mg
	Diary No. Date of R& I & fee	Dy.No 2376 dated 25-01-2023 Rs.30,000/- dated 23-01-2023(slip No. 570206386)
	Pharmacological Group	Anthelmintic, antiparasite
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml: Decontrolled
	Me-too status	Elvomec Star Injection 3.15% (10ml, 50ml, 100ml) of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063728)
	GMP status	GMP of relevant section
	Remarks of the Evaluator	**Injectable section** confirmed vide letter No. F.1-26/93-Lic (Vol. I)(M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Choice of only one pack size.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Choice of only one pack size** • **Latest GMP inspection report conducted within the period of last three years.**	
1389.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Top Bro Liquid
	Composition	Each 100ml contains: Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 2375 dated 25-01-2023 Rs.30,000/- dated 23-01-2023 (slip No. 85761971218)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5L: Decontrolled
	Me-too status	Ebrom-Lytic 10% Oral Liquid of M/s Vetec Laboratories, Rawalpindi. (Reg. No. 099317)
	GMP status	GMP of relevant section
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Confirmation of **relevant manufacturing facility**.
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
1390.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Doxymycin Powder
	Composition	Each gram contains: Erythromycin…200mg Doxycycline HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 2378 dated 25-01-2023 Rs.30,000/- dated 23-01-2023 (slip No. 631624275)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Ery Dox Powder of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan (Reg. No. 046619)
	GMP status	GMP of relevant section
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Confirmation of **relevant manufacturing facility**.
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
1391.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Le Procin Powder
	Composition	Each Kg contains: **Procaine Penicillin**…12gm **Streptomycin Sulphate**…36gm **Zinc Bacitracin**…52gm **Neomycin Sulphate**…10gm
	Diary No. Date of R& I & fee	Dy.No 2374 dated 25-01-2023 Rs.30,000/- dated 23-01-2023 (slip No. 0819756455)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	PSB-Excel Powder of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 082489)
	GMP status	GMP of relevant section
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Confirmation of **relevant manufacturing facility**.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1392.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Procolicin Powder
	Composition	Each Kg contains: **Procaine Penicillin**…12gm **Streptomycin Sulphate**…36gm **Zinc Bacitracin**…52gm **Neomycin Sulphate**…10gm **Colistin Sulphate**…60,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 2377 dated 25-01-2023 Rs.30,000/- dated 23-01-2023 (slip No. 0125773896)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	**Could not be confirmed in the applied combination and strength**
	GMP status	GMP of relevant section

	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Confirmation of **relevant manufacturing facility**. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

b. Deferred Cases

1393.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Maxofar Injection
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 28969 dated 22-10-2021 Rs.30,000/- dated 15-10-2021 (slip No. 72927892)
	Pharmacological Group	Antipyretic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	**10ml, 20ml, 50ml**; Decontrolled
	Me-too status	Fluxim-5% Injection (10ml: Reg. No. 109941; 20ml:109942; and 50ml: 109943) of M/s Univet Pharmaceuticals, Rawalpindi.
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Title of the firm mentioned on DML is "***M/s Izfaar Pharmaceutical Industries***" while "***M/s Izfaar Pharmaceutical Pvt. Ltd."*** is mentioned on form-5 and fee challan; clarify.
	Decision of 330th meeting: Deferred for following: • Latest GMP inspection report conducted within the period of last three years. • Choice of only one pack size. • Revised form-5 along with fee of Rs.30000/- for correction in formulation (salt form) in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 • Clarification regarding title of the firm since on DML "*M/s Izfaar Pharmaceutical Industries*" while "*M/s Izfaar Pharmaceutical Pvt. Ltd."* is mentioned on form-5 and fee challan. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the following:	

	• GMP certificate based upon evaluation conducted on 02-07-2021 • Demanded pack size: **10ml** • **Me-too/generic status:** Floxon Injection 10ml of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119707) • Firm has revised the label claim as following **Each ml contains:** **Flunixin as Meglumine.....50mg** • The firm has submitted fee Rs. 30,000/- dated 21-02-2024 vide challan No. 02936402373 for correction of label claim in line with reference product. • Firm has submitted copy of letter No F. 1-29/2007-Lic dated 09th October, 2017 for change of title from *M/s Izfaar Pharmaceutical Industries*" to "*M/s Izfaar Pharmaceutical Pvt. Ltd"*	
	Decision: Approved with following label claim in 10ml pack size: **Each ml contains:** **Flunixin as Meglumine.....50mg**	
1394.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Atrosol Injection
	Composition	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 2558 dated 24-02-2020 Rs.20,000/- dated 21-02-2020
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Atrapin Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112240)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision of 324th meeting: Deferred for evidence of approval of applied formulation for veterinary used in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Updated status: The firm has submitted the following generic status: **Me-too/generic status:** Atrobar Injection 50ml of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117369) **RRA status:** Atropine 0.1% pro inj., 1 mg/ml solution for injection for dogs and cats. (**The Netherlands approved**).	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1395.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	TYFENIC-30 Oral Liquid
	Composition	Each 100 ml contains Florfenicol…….30g
	Diary No. Date of R& I & fee	Dy No.11644: 06.03.2019 Rs. 20,000/-: 01.03.2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Firm has claimed In-house specification
	Pack size & Demanded Price	100 ml, 500 ml, 1 Litre, 2.5 Litre, 5 Litre : As per Policy of MoH

	Me-too status	N/A
	GMP status	Could not be confirmed
	Remarks of the Evaluator	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Previous decision	The board in its 290th meeting deferred the case for confirmation of me-too product
	Evaluation by PEC	• The firm revised the formulation from Each 100 ml contains Florfenicol…….30g To **Each 100 ml contains** **Florfenicol…….25g** **Colistin sulphate… 50 MIU** without submission of fee. • The firm submitted the following me too: Florotin-25. Reg. No. 93840, which is not available in the database. • The firm did not revise the manufacturing outlines and finished product specifications.
	Decision of 312th meeting: Deferred for the following: • Submission of fresh Form 5 along with all supported documents as per annexure and submission of fee. • Confirmation of generic status.	
	Updated status: The firm has submitted the following: ➢ Fresh Form 5 along with all supported documents ➢ **Proposed pack size**: 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml,5000ml ➢ **Me-too/generic status:** Tye-Fol Liquid of M/s Farm Aid Group, Haripur. (Reg. No. 092176) **Shortcomings:** The firm has **NOT** submitted fee for revision of formulation.	
	Decision: Approved with following label claim: **Each 100ml contains:** **Florfenicol…….25g** **Colistin sulphate… 50 MIU** **The firm shall submit following before issuance of registration letter:** • **fee Rs. 30,000/- for correction of label claim in line with reference product** • **latest GMP inspection report conducted within period of last three years**	
1396.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Trilev-Sc Drench
	Composition	Each ml contains: Triclabendazole…120mg Levamisole……75mg Sodium Selenite…0.35mg Cobalt Sulphate…0.75mg
	Diary No. Date of R& I & fee	Dy.No 5558 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antiplatyhenmintics/ Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 450ml, and 1000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Not submitted
	Remarks of the Evaluator	**Oral Liquid (G) Veterinary** section confirmed vide panel inspection dated 22-08-2022 for renewal of DML. **Shortcomings:**

		• Latest cGMP inspection report (conducted within the period of last three years) is required. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product and adjust its weight as per salt factor in master formula accordingly. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Full fee of registration for revision of label claim/ master formula, and finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision of 323rd meeting: Deferred for the following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. Latest GMP Inspection report conducted within last three years.	
	Updated status: The firm has submitted the following: ➢ **Me-too/generic status:** Tenxazole12% Oral Suspension of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111356) **Shortcomings:** ➢ Latest GMP Inspection report conducted within last three years. ➢ fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP Inspection report conducted within last three years.** • **fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1397.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Valron Injection 50ml
	Composition	Each ml contains: **Diclofenac Sodium**…100mg
	Diary No. Date of R& I & fee	Dy.No 4071 dated 04-02-2021 Rs.20,000/- dated 04-02-2021
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit

		panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 329th meeting: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. The Board further decided that the applicant shall submit the response within 1month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted reply dated 05-03-2024 ➢ cGMP certificate dated 02-01-2024 based upon evaluation conducted on 22-08-2023 & 14-09-2023 ➢ Liquid Injectable Section (G) Veterinary section confirmed vide letter No. F. 1-17/90-Lic (Vol-II) dated 29-02-2024 for renewal of DML. ➢ The firm has revised formulation as per below mentioned label claim without submission of fee. **Each ml contains:** **Diclofenac Sodium…50mg** ➢ Me-too/generic status: Diclostar Injection of M/s Star Laboratories (Pvt) Ltd Lahore (Reg. No. 026503) **Shortcomings:** ➢ Full fee of registration for revision of label claim in line with reference formulation and finished product specifications.	
	Decision: Registration Board rejected the instant application for registration of veterinary drug since safer and more effective alternatives, such as Meloxicam, are freely available.	
1398.	Case was deleted due to duplication.	
1399.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Amoxy Add Water Soluble Powder
	Composition	Each Kg contains: Amoxicillin Trihydrate…50gm Lysozyme Chloride…10gm Guaifenesin…35gm
	Diary No. Date of R& I & fee	Dy.No 12320 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form 5
	Finished product Specifications	**Not mentioned**
	Pack size & Demanded Price	**Not mentioned**; Decontrolled
	Me-too status	Amoxy Add Water Soluble Powder of M/s Samyang Anipharm Co., Seoul, Korea (Reg. No. 069649)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Oral powder (Penicillin) Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018. **Shortcomings:** • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide Master formulation describing quantities of actives and excipients along with their justification/ role of ingredients.

		• Provide outline of method of manufacturing. • "Pack size" is not mentioned in form-5.
	Decision of 326th meeting: Deferred for following: • rationality and solubility of formulation • finished product specifications in the light of decision taken in 267th meeting of Registration Board. • master formulation describing quantities of actives and excipients alongwith their justification/role of ingredients. • outline of method of manufacturing. • demanded pack size	
	Updated status: The firm has submitted the following: ➢ "It is submitted that the subject product is **not a Water soluble powder** rather it is a powder in dosage form that was a typographic mistake by the company representative. ➢ Revised FPP specifications to **as per innovator's specifications** ➢ Demanded Pack Size: 100gm, 250gm, 500gm, 1000gm, 10000gm ➢ Master formulation and outline of method of manufacturing **Shortcomings:** ➢ Fee Rs. 7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. ➢ Latest GMP Inspection report conducted within last three years.	
	Decision: Approved with change of brand name. Firm shall submit following before issuance of registration letter: • **fee Rs. 7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Latest GMP Inspection report conducted within last three years.**	
1400.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Rectin-D.S Injection
	Composition	Each ml contains: Ivermectin…….12mg
	Diary No. Date of R& I & fee	Dy.No 188 dated 23-06-2011, Rs.8,000/- and Rs.12,000/- vide Dy. No. 79 dated 11-09-2013
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Not provided
	Pack size & Demanded Price	10ml, 30ml, 50ml, 100ml, 500ml: Decontrolled
	Me-too status	
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	• **Veterinary Liquid injection (General) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008
	Decision of 254th meeting: Deferred for following: • Finished product specifications are not provided. • Calculations in salt and base are not provided. • Last inspection report conducted within period of 1 year is not provided. • Commitment as per the decision of Board is not provided. • Outline method of manufacture is not provided. • Complete description of formulation is not provided. • The firm has submitted single page stability data without any supporting documents. • Formulation requires justifications as no buffering agents are added to stabilize the formulation. • Only one volume requires to be applied per application as per the decision of Board.	
	Updated status: The firm has submitted the following:	

	➢ The firm has revised formulation as per below mentioned label claim along with fee Rs. 30,000/- dated 11-03-2024 for revision of formulation vide challan No. 774731414587 **Each ml contains:** **Ivermectin…….20mg** ➢ Me-too status: Selmec Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071087) ➢ Demanded pack size: **50ml** **Shortcomings:** ➢ Master formulation and outline of method of manufacturing	
	Decision: Approved with following label claim in 50ml pack size: **Each ml contains:** **Ivermectin…….20mg** **Firm shall submit** **Firm shall submit following before issuance of registration letter:** • **latest GMP inspection report conducted within period of last three years.** • **Master formulation and outline of method of manufacturing before issuance of registration letter.**	
1401.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Fosfabak-Plus Powder
	Composition	Each gram Contains: Fosfomycin Calcium…200mg Tylosin Tartrate…50mg Dextrose…180mg Sodium Phosphate…150mg Magnesium phosphate…100mg Sodium Chloride q.s.…1000mg
	Diary No. Date of R& I & fee	Dy.No 15140 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 98874800789)
	Pharmacological Group	Antibacterial/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm; Decontrolled
	Me-too status	**Could not be confirmed in the applied combination**
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator	Approval of **Oral Powder Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 329th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the following: **Me-too/generic status:** Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626) • The reference formulation is **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg**	

	Magnesium Phosphate…100mg **Sodium chloride q.s .....1000mg** **Shortcomings:** ➢ Firm shall submit fee of Rs.30000/- for revision of label claim in line with reference formulation.	
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium chloride q.s .....1000mg** **Firm shall submit following before issuance of registration letter:** • **latest GMP inspection report conducted within period of last three years.** • **fee of Rs.30000/- for revision of label claim in line with reference formulation.**	
1402.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1 km towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	OPT Injection I/M, I/V, S/C
	Composition	Each 100ml contains: Oxytetracycline HCl……..5gm **Prednisolone Acetate**……..…500mg Tylosin Tartrate……...10gm
	Diary No. Date of R& I & fee	Dy.No.26771-A dated 03-08-2018 Rs.20,000/- Dated 03-08-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form- 5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	50ml & Decontrolled
	Me-too status	Tylo OP Injection of M/s Leads Pharma (Pvt.) Ltd., Islamabad (Reg. # 041216)
	GMP status	Last GMP inspection was conducted on 02-03-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator	• Liquid injectable (Veterinary) is available in the firm as mentioned in the submitted GMP inspection report.
	Decision of 292nd meeting: Registration Board deferred the application for verification of section/manufacturing facility for "Liquid Injection (steroidal)" section.	
	Updated status: The firm has submitted the evidence of **Liquid Injectable Veterinary (steroid)** section confirmed vide letter No.F. 1-14/2002-Lic (vol-I) dated 07-06-2022. **Shortcomings:** ➢ Formulation already referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Target species**	
1403.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cepfur Sterile Powder for Injection
	Composition	Each vial contains: Ceftiofur as Sodium…1gm
	Diary No. Date of R& I & fee	Dy.No 7566 dated 29-05-2019 Rs.20,000/- dated 27-05-2019

	Pharmacological Group	Antibacterial (Cephalosporin)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1's x 1gm; Decontrolled
	Me-too status	Ceftiofur Sodium for Injection of M/s Mehran International, Karachi (Reg. No. 049573)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Firm has revised finished product specification from inhouse **to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 35787178.**
	Decision of 323rd meeting: Deferred for approval of requisite manufacturing facility / section.	
	Updated status: The firm has submitted the following: **Dry Powder for Injection (Cephalosporin-Veterinary)-Additional** section confirmed vide letter No.F. 1-27/85-Lic (vol-II) dated 24-04-2024	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within period of last three years before issuance of registration letter.	
1404.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Bromocin Powder
	Composition	Each 100gm Powder Contains: Lincomycin as HCl…5g Colistin Sulphate…50MIU Amoxicillin Trihydrate…10g Bromhexine HCl…0.5g
	Diary No. Date of R& I & fee	26772-J dated 03-08-2018 Rs.20,000/- Dated 03-08-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 25 kg Decontrolled
	Approval status of product in RRAs	NA
	Me-too status	MOXIN-L water soluble powder of Atabak Pharama (071053)
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator	
	Decision of 287th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Updated status: The firm has already submitted the following metoo status: **Me-too/generic status:** MOXIN-L water soluble powder of Atabak Pharama (071053)	
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **fee Rs. 7500/- for revision of finished product specifications** • **latest GMP inspection report conducted within period of last three years**	
1405.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Respityl-C Oral Powder

	Composition	Each 100gm contains: - Doxycycline HCL … 40 gm Tylosin Tartrate …20 gm Colistin Sulphate …10 MIU Bromhexine HCl …2 gm
	Diary No. Date of R& I & fee	Dy.No:31086 , dated:12-11-2021, Rs.30,000/-, dated: 11-11-2021
	Pharmacological Group	Antibiotic, Mucolytic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	100gm,500gm,1 Kg,5Kg,10Kg, 25Kg./ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	MULTIDOX ORAL POWDER REG.# 078395 HAWK BIO PHARMA ISLAMABAD.
	GMP status	GMP inspection held on 14-10-2021 Panel Inspection Panel recommended the approval of 4 additional sections
	Remarks of the Evaluator	Firm has applied Colistin Sulphate …10 MIU in Form-5, whereas, me-too contains Colistin Sulphate …10 gm.
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too MULTIDOX ORAL POWDER Reg. No. 078395, with submission of fee of Rs.7500/- vide challan no. 32594204089 as: **Each 100gm contains:** **Doxycycline HCl ……40gm** **Tylosin Tartrate ……20gm** **Colistin Sulphate …..10gm** **Bromhexine HCl ...2gm** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each 100gm contains:** **Doxycycline HCl ……40gm** **Tylosin Tartrate ……20gm** **Colistin Sulphate ….10gm** **Bromhexine HCl ...2gm** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1406.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Brom-CTD Water Soluble Powder
	Composition	Each gm contains: - Doxycycline HCl ….100 mg Tylosin Tartrate …100 mg Colistin Sulphate …25, 00,000 IU Bromhexine HCl …5mg
	Diary No. Date of R& I & fee	Dy.No:31088 , dated:12-11-2021, Rs.30,000/-, dated: 11-11-2021
	Pharmacological Group	Antibiotic, Mucolytic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification

	Pack size & Demanded Price	100gm,500gm,1 Kg,5Kg,10Kg, 25Kg./ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	DOXIMAC-C WATER SOLUBLE POWDER REG.#049530 PRIX PHARMACEUTICA (PVT) LTD., LAHORE.
	GMP status	GMP inspection held on 14-10-2021 Panel Inspection Panel recommended the approval of 4 additional sections
	Remarks of the Evaluator	Firm has applied Doxycycline HCl ….100 mg, whereas, me-too contains Doxycycline Hyclate ….100 mg.
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too DOXIMAC-C Water Soluble Powder Reg. No. 049530, with submission of fee of Rs.7500/- vide challan no. 858295532520 as: **Each Gm contains: -** **Colistin Sulphate …25,00,000IU** **Tylosin (As Tartrate) …… 100mg** **Doxycycline (As Hyclate) …100mg** **Bromhexine (As Hydrochloride) ….....5mg** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each Gm contains: -** **Colistin Sulphate …25,00,000IU** **Tylosin (As Tartrate) …… 100mg** **Doxycycline (As Hyclate) …100mg** **Bromhexine (As Hydrochloride) ….....5mg** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1407.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	DI-BP Benz Injection (10ml)
	Composition	Each ml contains: Benzathine Penicillin G …100,000IU Procaine Penicillin …15,000IU Streptomycin sulphate …200mg
	Diary No. Date of R& I & fee	Dy No: 31176, Dated:12-11-2021, Rs. 30,000, Dated:11-11-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10ml/ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	B.G Probenz Injection REG.# 072699 Biogen Pharma,Rawat.
	GMP status	The Central Licensing Board in its 283rd meeting held on 28th October,2021 has considered and approved the four (04) additional sections in the name of M//s Eterna Pharma (Pvt.)Ltd.Plot#(99,100,101,198)C,Sector D1,Old Industrial Estate, Mirpur,Azad Jammu & Kashmir by way of

		Formulation vide approval letter No. F. 5-1/2016- Lic dated 11th November, 2021.
	Remarks of the Evaluator	• Me-too status not confirms from available database. Composition of submitted me-too i.e B.G Probenz Injection by M/s. Biogen Pharma,Rawat (Reg#072699) is: Each ml contains: Benzathine Penicillin G …100,000 IU Procaine Penicillin G …150,000 IU Dihydrostreptomycin Sulphate …200 mg
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too B.G Probenz Injection Reg. No. 072699, with submission of fee of Rs.7500/- vide challan no. 13470795 as: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1408.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	DI-BP Benz Injection (30ml)
	Composition	Each ml contains:- Benzathine Penicillin G …100,000IU Procaine Penicillin …15,000IU Dihydrostreptomycin sulphate …200mg
	Diary No. Date of R& I & fee	Dy No: 31177, Dated:12-11-2021, Rs. 30,000, Dated:11-11-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	30ml/ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	B.G Probenz Injection REG.# 072699 Biogen Pharma,Rawat.
	GMP status	The Central Licensing Board in its 283rd meeting held on 28th October,2021 has considered and approved the four (04) additional sections in the name of M//s Eterna Pharma (Pvt.)Ltd.Plot#(99,100,101,198)C,Sector D1,Old Industrial Estate, Mirpur,Azad Jammu & Kashmir by way of Formulation vide approval letter No. F. 5-1/2016- Lic dated 11th November, 2021.
	Remarks of the Evaluator	• Me-too status not confirms from available database.

		Composition of submitted me-too i.e B.G Probenz Injection by M/s. Biogen Pharma,Rawat (Reg#072699) is: Each ml contains: Benzathine Penicillin G …100,000 IU Procaine Penicillin G …150,000 IU Dihydrostreptomycin Sulphate …200 mg
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too B.G Probenz Injection Reg. No. 072699, with submission of fee of Rs.7500/- vide challan no. 00449957851 as: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1409.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	**DI-BP Benz Injection (50ml)**
	Composition	Each ml contains:- Benzathine Penicillin G …100,000IU Procaine Penicillin …15,000IU Dihydrostreptomycin sulphate …200mg
	Diary No. Date of R& I & fee	Dy No: 31178, Dated:12-11-2021, Rs. 30,000, Dated:11-11-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	50ml/ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	B.G Probenz Injection REG.# 072699 Biogen Pharma,Rawat.
	GMP status	The Central Licensing Board in its 283rd meeting held on 28th October,2021 has considered and approved the four (04) additional sections in the name of M//s Eterna Pharma (Pvt.)Ltd.Plot#(99,100,101,198)C,Sector D1,Old Industrial Estate, Mirpur,Azad Jammu & Kashmir by way of Formulation vide approval letter No. F. 5-1/2016- Lic dated 11th November, 2021.
	Remarks of the Evaluator	• Me-too status not confirms from available database. Composition of submitted me-too i.e B.G Probenz Injection by M/s. Biogen Pharma,Rawat (Reg#072699) is:

		Each ml contains:- Benzathine Penicillin G …100,000 IU Procaine Penicillin G …150,000 IU Dihydrostreptomycin Sulphate …200 mg
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too B.G Probenz Injection Reg. No. 072699, with submission of fee of Rs.7500/- vide challan no. 77488923167 as: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G….....150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1410.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198) C, Sector D1,Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	DI-BP Benz Injection (100ml)
	Composition	Each ml contains:- Benzathine Penicillin G …100,000IU Procaine Penicillin …15,000IU Dihydrostreptomycin sulphate …200mg
	Diary No. Date of R& I & fee	Dy No: 31179, Dated:12-11-2021, Rs. 30,000, Dated:11-11-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	100ml/ Decontrolled
	Approval status of product in RRAs	N/A
	Me-too status	B.G Probenz Injection REG.# 072699 Biogen Pharma,Rawat.
	GMP status	The Central Licensing Board in its 283rd meeting held on 28th October,2021 has considered and approved the four (04) additional sections in the name of M//s Eterna Pharma (Pvt.)Ltd.Plot#(99,100,101,198)C,Sector D1,Old Industrial Estate, Mirpur,Azad Jammu & Kashmir by way of Formulation vide approval letter No. F. 5-1/2016- Lic dated 11th November, 2021.
	Remarks of the Evaluator	• Me-too status not confirms from available database. Composition of submitted me-too i.e B.G Probenz Injection by M/s. Biogen Pharma,Rawat (Reg#072699) is: Each ml contains:- Benzathine Penicillin G …100,000 IU Procaine Penicillin G …150,000 IU

		Dihydrostreptomycin Sulphate …200 mg
	Decision of 316th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: Firm has revised the label claim in line with mee-too B.G Probenz Injection Reg. No. 072699, with submission of fee of Rs.7500/- vide challan no. 88180508 as: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G…..150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each ml contains:** **Benzathine Penicillin G……100,000 IU** **Procaine Penicillin G…..150,000 IU** **Dihydrostreptomycin Sulphate……200mg** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1411.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Intro-Vitc 100 Powder
	Composition	Each 100gm Contains: Vitamin C…100% w/w
	Diary No. Date of R& I & fee	Dy. No. 30858-G dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm,25gm,50gm, 100gm, 150gm, 200gm, 250gm, 500gm,1kg, 2.5kg,5kg,10kg,15kg,20kg,25kg :Decontrolled
	Me-too status	C.Vit Forte Powder Of Syamans Pharmaceuticals (Pvt) Ltd Lahore (025315)
	GMP status	
	Remarks of the Evaluator	
	Decision of 293rd meeting: Deferred for clarification regarding amount of following API in applied formulation: Vitamin C 100% w/w/ 100gm powder	
	Updated status: The firm has submitted the following: "It is hereby certified that our product name is Intro-VitC 100 powder composition Each 100gram contains Vitamin C……100% w/w (nutritional agent) in which vitamin C 100% w/w is equal to 100grams. Submitted for consideration of the Board.	
	Decision: Approved for use in poultry only. Firm shall submit fee Rs. 7,500/- for revision of FPP specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1412.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ismedine Bolus
	Composition	Each Bolus Contains: Sulphadimidine…350mg

	Diary No. Date of R& I & fee	Dy. No 10650 dated 05-11-2020 Rs.20,000 dated 04-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5x 10's blister in unit carton: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance
	Remarks of the Evaluator	**Tablet Bolus (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision of 324th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
	Updated status: The firm has submitted the following: **Me-too/generic status:** Sulf-B Bolus of M/s International Pharma Labs. Lahore. (073930) **Each bolus contains:** **Sulphadimidine HCI…350mg** **Shortcomings:** Firm shall submit fee Rs.30,000/- for pre-approval revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with following label claim: **Each bolus contains:** **Sulphadimidine HCI…350mg** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1413.	Name and address of manufacturer / Applicant	International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1Km Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Dairy Supplement Granules Powder
	Composition	Each Kg contains: Calcium…….....155gm Phosphorus……...135gm Magnesium…….....55gm Sodium…….45gm Iron……1gm Zinc……..……...…..3gm Manganese…….....2gm Copper……..0.6gm Cobalt……..…0.01gm Iodine……0.04gm selenium……0.003gm
	Diary No. Date of R& I & fee	Dy. No 202 dated 27-8-2015 Rs. 20,000 dated 26-8-2015
	Pharmacological Group	Minerals
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5gm,10gm, 20gm, 50gm, 100gm, 200gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 20000gm, 25000gm; Decontrolled
	Me-too status	L.S. MINERALS POWDER NAWAN LABS KARACHI (Could not be confirmed)
	GMP status	GMP inspection dated 16-10-2018 concludes that firm was operating at fair level of GMP Compliance.

	Remarks of the Evaluator	
	Previous decision	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-285).
	Evaluation by PEC	The firm has submitted following me-too reference which has been verified. SP MINERALS GRANULES of M/s Selmore Pharma (Reg#088154)
	Decision of 291st meeting: Deferred for confirmation of source of minerals of applied formulation.	
	Updated status: The firm has declared that the source of minerals is **China** without providing any documented evidence.	
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **declaration regarding origin/ source of minerals, whether animal origin or synthetic** • **fee Rs. 7,500/- for revision of FPP specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1414.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 10ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 22617 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 6768206298)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Could not be confirmed in the applied strength and pack size
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 330th meeting: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Updated status: The firm has revised formulation as per below mentioned label claim without submission of fee. **Each ml contains:** **Vitamin A……...…… 100,000 IU** **Vitamin D3……...……. 40,000 IU** **Vitamin E…….…….…...40mg** **Me-too/generic status:** ADEKA Injection (10ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792) **Shortcomings:** Full fee of registration for revision of label claim in line with reference formulation and finished product specifications.	
	Decision: Approved with following label claim: **Each ml contains:** **Vitamin A……...…… 100,000 IU** **Vitamin D3……...……. 40,000 IU**	

	Vitamin E…….…….…...40mg **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1415.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 100ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 22618 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 646015370135)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Could not be confirmed in the applied strength and apck size
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 330th meeting: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Updated status: The firm has revised formulation as per below mentioned label claim without submission of fee. **Each ml contains:-** **Vitamin A……...…..….100,000 IU** **Vitamin D3……...…….40,000 IU** **Vitamin E…….…….…...40mg** **Me-too/generic status:** Ad Vetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 117207) **Shortcomings:** Full fee of registration for revision of label claim in line with reference formulation and finished product specifications.	
	Decision: Approved with following label claim: **Each ml contains:** **Vitamin A……...…..…. 100,000 IU** **Vitamin D3……...……. 40,000 IU** **Vitamin E…….…….…...40mg** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1416.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 50ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg

	Diary No. Date of R& I & fee	Dy.No 22619 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 59220361316)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 330th meeting: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Updated status: The firm has revised formulation as per below mentioned label claim without submission of fee. **Each ml contains:-** **Vitamin A……...…..….100,000 IU** **Vitamin D3……...…….40,000 IU** **Vitamin E…….…….…...40mg** **Me-too/generic status:** Vital Forte Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited Lahore (Reg. No. 118456) **Shortcomings:** Full fee of registration for revision of label claim in line with reference formulation and finished product specifications.	
	Decision: Approved with following label claim: **Each ml contains:** **Vitamin A……...…… 100,000 IU** **Vitamin D3……...……. 40,000 IU** **Vitamin E…….…….…...40mg** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	

Case no. 02 Registration applications of import cases

a. New Cases (Veterinary)

1417.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34279 Dated 28-11-2022
	Fee including differential fee	Rs : 150,000 Dated 14-11-2022 (slip No. 345358908424)

	Brand Name +Dosage Form + Strength	MS-AMO50 Water soluble powder
	Composition	Each gram contains: Amoxicillin as trihydrate…500mg
	Finished Product Specification	CVP
	Pharmacological Group	Beta lactam antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	0.5Kg, 1Kg, 2.5Kg
	International availability	N/A
	Me-too status	Amcin-50 Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093791)
	Detail of certificates attached	➢ Scanned copy of COPP No. 2021-00612 dated 20-12-2021 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 24-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Copy of valid DSL • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility for penicillin production lines**
	Decision: Deferred for following: • **Copy of valid DSL** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP** • **Confirmation of dedicated manufacturing facility for penicillin production lines.**	
1418.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 22946 Dated 15-08-2022
	Fee including differential fee	Rs : 150,000 Dated 10-08-2022 (slip No. 652353585928)
	Brand Name +Dosage Form + Strength	MS-AMO20 Injection
	Composition	Each ml contains:

		Amoxicillin (Amoxicillin Trihydrate)…200mg
	Finished Product Specification	CVP
	Pharmacological Group	Beta lactam antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	**50ml, 100ml, 500ml**
	International availability	N/A
	Me-too status	V-Mox L.A 20% Injection **(100ml)** of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 084968)
	Detail of certificates attached	➢ Scanned copy of COPP No. 2019-00050 dated 20-05-2020 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 24-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Copy of valid DSL • Choice of only one pack size • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility for penicillin production lines**
	Decision: Deferred for following: • **Copy of valid DSL** • **Choice of only one pack size** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP** • **Confirmation of dedicated manufacturing facility for penicillin production lines.**	
1419.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 22947 Dated 15-08-2022
	Fee including differential fee	Rs : 150,000 Dated 10-08-2022 (slip No. 27115497)
	Brand Name +Dosage Form + Strength	MS-Coli for Oral Administration
	Composition	Each gram contains:

		Colistin sulfate…9,000,000IU
	Finished Product Specification	CVP
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	0.5Kg, 1Kg, 5Kg
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Scanned copy of COPP No. 2020-00082 dated 01-07-2021 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 24-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Copy of valid DSL • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Copy of valid DSL** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1420.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5095 Dated 22-02-2023
	Fee including differential fee	Rs : 150,000 Dated 09-02-2023 (slip No. 29500618533)
	Brand Name +Dosage Form + Strength	MS-Flor 20 Oral Solution
	Composition	Each ml contains: Florfenicol…200mg
	Finished Product Specification	CVP

	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1L, 2.5L, 5L
	International availability	N/A
	Me-too status	Florfen-20% oral liquid of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 074091)
	Detail of certificates attached	➢ Scanned copy of COPP No. 2021-00624 dated 20-12-2021 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 24-month real time **(25±2ºC/ 65±5%RH)** stability studies data of three batches. **Shortcomings:** • Copy of valid DSL • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • Long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life.
	Decision: Deferred for following: • **Copy of valid DSL** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP** • **Long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life.**	
1421.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33420 Dated 21-11-2022
	Fee including differential fee	Rs : 75,000 Dated 02-11-2022 (slip No. 71955365481)
	Brand Name +Dosage Form + Strength	Sealer Injection
	Composition	Each gram contains: Bismuth Subnitrate…650mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Drug for intra-mammary use
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	4gram powder
	International availability	China

	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized COPP No. Vet. Drug No. 150257074 dated 21-07-2022 issued by Shandong Provincial Animal Husbandry & Veterinary Bureau, China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Scanned copy of legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years. **(original submitted with Gamicure Injection dossier)**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 36-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries.	
1422.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 10688, Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33421 Dated 21-11-2022
	Fee including differential fee	Rs : 75,000 Dated 02-11-2022 (slip No. 7794344782)
	Brand Name +Dosage Form + Strength	Gamicure Injection
	Composition	Each ml contains: Gamithromycin…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	China
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized COPP No. Vet. Drug No. 150252993 dated 21-07-2022 issued by Shandong Provincial Animal Husbandry & Veterinary Bureau, China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country.

		➢ Original legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 36-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status), or approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries.	
1423.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Arab Veterinary Industrial Co. ”AVICO” P.O.Box 150906, Amman 11115-Jordan
	Name and address of marketing authorization holder	M/s Arab Veterinary Industrial Co. ”AVICO” P.O.Box 150906, Amman 11115-Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2379 Dated 25-01-2023
	Fee including differential fee	Rs : 150,000 Dated 28-12-2022 (slip No. 63320314461)
	Brand Name +Dosage Form + Strength	Avico Fosfomycin Powder for Oral Use
	Composition	Each gram contains: Calcium Fosfomycin…200mg Tylosin Tartrate…50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	500gm, 1Kg
	International availability	N/A
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	Detail of certificates attached	➢ Original Legalized COPP NO. 000107 dated 05-01-2021 issued by the Ministry of Agriculture, The Hashemite Kingdom of Jordan confirms GMP status and Free sale status of applied product in country of origin. ➢ Photocopy of LOA attached. (**original legalized power of attorney dated 30-08-2023 already submitted with reply of Diaban Suspension considered in 331st meeting of Registration Board**).
	Remarks of the Evaluator [XXV]	The firm has provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-A conditions.
	Decision: Approved subject to compliance to current import policy for finished drugs.	

1424.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name and address of marketing authorization holder	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name of exporting country	Portugal
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 29610 Dated 18-10-2022
	Fee including differential fee	Rs : 150,000 Dated 03-10-2022 (slip No.66048168287)
	Brand Name +Dosage Form + Strength	Tilfur WS 1000 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100gm, 500gm and 1000gm
	International availability	N/A
	Me-too status	Tylokam-100 Soluble Powder of M/s M. A. Kamil Farma (Pvt) Ltd., Karachi. (Reg. No. 119729)
	Detail of certificates attached	➢ **Unattested photocopy** of CoPP No. 602/CMVPT/2022 certified by The General Directorate of Food and Veterinary for Importing country **EGYPT** ➢ Photocopy of declaration **(not legalized)** dated 10-08-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [XXV]	The firm **has not provided** stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is **copy not even notarized.** • legalized original valid CoPP since already submitted is **unattested copy not issued for Pakistan**. • 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even notarized.** • **legalized original valid CoPP since already submitted is unattested copy not issued for Pakistan.** • **06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.**	

1425.	Name and address of Applicant	M/s ZS Biotech, **Head office address**: 50-C, Madina Block, Awan Town, Multan Road, Lahore, Pakistan. **Warehouse address:** 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore.
	Detail of Drug Sale License	Name: M/s ZS Biotech Address: House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore. **Validity: 20-01-2024.** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Better Pharma Co., Ltd., **Factory address:** 216, Moo 1, Saraburi-Lomsak Road, Chongsarika, Pattananikhom, Lopburi 15220, Thailand.
	Name and address of marketing authorization holder	M/s Better Pharma Co., Ltd., **Head office address:** Betagro Tower (North Park), 323 Vibhavadi Rangsit Road, Laksi, Bangkok, 10210, Thailand **Factory address:** 216, Moo 1, Saraburi-Lomsak Road, Chongsarika, Pattananikhom, Lopburi 15220, Thailand.
	Name of exporting country	Thailand, Bangkok
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 23366 Dated 18-08-2022
	Fee including differential fee	Rs : 1,50,000 Dated 17-08-2022 (slip No. 75500711657)
	Brand Name +Dosage Form + Strength	Comoxy 500 WSP
	Composition	Each Kg contains: Amoxicillin Trihydrate eq. to Amoxicillin…100gm Colistin Sulphate Eq. to Colistin…400 MIU
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100gm, 200gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg and 25Kg
	International availability	Philippines
	Me-too status	Amoxicoli Water Soluble Powder of M/s Hassan Brothers, Faisalabad. (Reg. No. 082805)
	Detail of certificates attached	• Copy of legalized FSC No. 1-2-03-03-20-00397 dated 28-05-2020 issued by the Food and Drug Administration, Ministry of Public Health, Thailand confirms free sale status of the product in country of origin. Validity: **27-05-2022** • Copy of legalized GMP certificate No. 1-2-07-17-18-00032 dated 28-11-2017 issued by the Medicines Regulation Division, Food and Drug Administration, Ministry of Public Health Thailand confirms GMP status of the manufacturing site for **non-sterile Penicillin Products (Powders).** Validity: 27-11-2020 • Copy of original legalized distribution agreement made on 01-12-2020 between the applicant and product license holder is provided. Validity: **31-12-2024** (**Original legalized distribution agreement already submitted in DRAP with dossier Tylin Oral Powder considered and approved in 330th meeting)**

	Remarks of the Evaluator [XXV]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Copy of **valid DSL** • Submit legalized original valid FSC, since the already submitted copy is ***expired even upon submission.*** • Submit legalized original valid GMP certificate since the already submitted is ***expired even upon submission.*** • Firm shall submit fee for pre-approval revision of label claim in line with reference product.
	Decision: Deferred for following: • **Copy of valid DSL** • **legalized original valid FSC, since the already submitted copy is expired even upon submission.** • **legalized original valid GMP certificate since the already submitted is expired even upon submission.** • **fee for pre-approval revision of label claim in line with reference product.**	
1426.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Vetviva Richter GmbH, Durisolstrabe 14, 4600 Wels, Austria
	Name and address of marketing authorization holder	M/s Vetviva Richter GmbH, Durisolstrabe 14, 4600 Wels, Austria
	Name of exporting country	Austria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 836 Dated 10-01-2023
	Fee including differential fee	Rs : 75,000 Dated 27-12-2022 (slip No. 54295145605)
	Brand Name +Dosage Form + Strength	Theranekron D6 Solution for Injection
	Composition	Each 1ml contains: Tarantula Cubensis D6…1ml
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Other therapeutic product
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml, 100ml, 250ml and 500ml
	International availability	N/A
	Me-too status	N/A
	Detail of certificates attached	-
	Remarks of the Evaluator [XXV]	The applied formulation is homeopathic medicine may be forwarded to the concerned Division, please.
	Decision: Registration Board disposed off the case as being possibly a homeopathic product. The applicant may apply to the concerned division for consideration.	
1427.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028.

		Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin Cootehill Co, Cavan Ireland
	Name and address of marketing authorization holder	M/s Bimeda Animal Health Limited 2, 3,& 4 Airton close, Airton Road Tallaght Dublin 24 Ireland.
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 37 Dated 02-01-2023
	Fee including differential fee	Rs : 75,000/- Dated 27-12-2022 (slip No. 511559016)
	Brand Name +Dosage Form + Strength	Multishield DC Intramammary Suspension for Cows
	Composition	Each 4.5gm Intramammary syringe contains: Neomycin 70,000 IU (corresponding to Neomycin Sulphate…100mg) Penethamate 77.2mg (corresponding to Penethamate Hydriodide…100mg) Benzyl Penicillin 227.2mg (corresponding to Procaine Benzyl Penicillin…400mg)
	Finished Product Specification	Inhouse
	Pharmacological Group	Combination of Beta lactam and aminoglycoside antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	4.5gm
	International availability	Ireland approved
	Me-too status	N/A
	Detail of certificates attached	➢ Original Legalized FSC No. FSC-22-0006 dated 28-02-2022 issued by HPRA Ireland confirms Free Sale status of the product in the exporting country. ➢ Copy of EUDRA GMP certificate No. 29062/V10864 issued on the basis of inspection conducted on 25-09-2020 with scope **small volume liquids (beta lactam antibiotics)** ➢ Copy of **Un-notarized** Power of attorney dated 15-11-2022 provided.
	Remarks of the Evaluator [XXV]	**Shortcomings:** • original notarized Power of attorney/sole agency certificate**.** • Original legalized valid GMP certificate • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions
	Decision: Deferred for submission of following: • **original notarized Power of attorney/sole agency certificate.** • **Original legalized valid relevant GMP certificate** • **06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions** • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise**	
1428.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4

	Name and address of marketing authorization holder	M/s Bimeda Animal Health Limited 2, 3,& 4 Airton close, Airton Road Tallaght Dublin 24 Ireland.
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 39 Dated 02-01-2023
	Fee including differential fee	Rs : 75,000/- Dated 26-12-2022 (slip No. 9884060441)
	Brand Name +Dosage Form + Strength	Embotape Oral Paste
	Composition	Each gram contains: Pyrantel Embonate…400mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	28.5gm and 57gm
	International availability	Ireland approved
	Me-too status	N/A
	Detail of certificates attached	➢ Original legalized GMP certificate No. 79477 dated 25-03-2025 issued by Health Canada ➢ **Free sale certificate (FSC) is not provided** by the firm. ➢ Original **Un-notarized** Power of attorney dated 15-11-2022 provided.
	Remarks of the Evaluator [XXV]	**Shortcomings:** • Original legalized valid FSC/ COPP • original notarized Power of attorney/sole agency certificate**.** • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions
	Decision: Deferred for submission of following: • **Original legalized valid FSC/ COPP** • **original notarized Power of attorney/sole agency certificate.** • **06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions**	
1429.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4
	Name and address of marketing authorization holder	M/s Bimeda Animal Health Limited 2, 3,& 4 Airton close, Airton Road Tallaght Dublin 24 Ireland.
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 38 Dated 02-01-2023
	Fee including differential fee	Rs : 75,000/- Dated 26-12-2022 (slip No. 0903499699)
	Brand Name +Dosage Form + Strength	Bimectin Horse Oral Paste
	Composition	Each gram contains: Ivermectin…18.7mg
	Finished Product Specification	Inhouse

	Pharmacological Group	Anthelmintic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	6.42gm
	International availability	Ireland approved
	Me-too status	N/A
	Detail of certificates attached	➢ Copy of original legalized GMP certificate No. 79477 dated 25-03-2025 issued by Health Canada ➢ **Free sale certificate (FSC) is not provided** by the firm. ➢ Copy of **un-notarized** Power of attorney dated 15-11-2022 provided.
	Remarks of the Evaluator [XXV]	**Shortcomings:** • Original legalized valid FSC/ COPP • original notarized Power of attorney/sole agency certificate**.** • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions
	Decision: Deferred for submission of following: • **Original legalized valid FSC/ COPP** • **original notarized Power of attorney/sole agency certificate.** • **06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions**	
1430.	Name and address of Applicant	M/s Biovision Corporation, Flat No.1, 69/4-F, Punjab Cooperative Housing Society, Defence Ghazi Road, Cantt. Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Biovision Corporation Address of Godown: Basement-543/10-E, PCHS, Defence Ghazi Road, Cantt. Lahore, Pakistan Validity: **05-03-2023**. Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Anvet Pharma JSC., B2-19 Plot, Tan Dong Hiep B, Industrial Park, Tan Dong Hiep Ward, Di An Town, Binh Duong Province, Vietnam
	Name and address of marketing authorization holder	M/s Anvet Pharma JSC., B2-19 Plot, Tan Dong Hiep B, Industrial Park, Tan Dong Hiep Ward, Di An Town, Binh Duong Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 25512 Dated 08-09-2022
	Fee including differential fee	Rs : 150,000/- Dated 06-09-2022 (slip No. 134090290711)
	Brand Name +Dosage Form + Strength	Enroflox Oral Solution
	Composition	Each 100ml contains: Enrofloxacin Base…20gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	500ml, 1L, 5L, 20L
	International availability	Oman, Myanmar, Syria, Iraq
	Me-too status	Quinrox-20 Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118642)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 523/2020/QLT-CFS issued by Ministry of Agriculture and

		Rural development department of Animal Health 15/78 GiaiPhong Street- DongDa- HaNoi- Vietnam Date of issuance: 18-06-2020 validity: 2 years ➢ Original legalized GMP certificate No. 26/17/GCN- GMP issued on 23-10-2017 and valid for 5 years. ➢ Original legalized Exclusive distribution agreement between M/s Biovision Corporation and M/s Anvet Pharma JSC., Vietnam
	Remarks of the Evaluator [XXV]	06 months accelerated and 24 months long term stability studies data of **only one batch** as per zone-IV-A conditions has been provided. **Shortcomings:** • Copy of valid **DSL** • Original legalized valid FSC since the already submitted is **expired even upon submission.** • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original legalized valid FSC since the already submitted is expired even upon submission.** • **06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
1431.	Name and address of Applicant	M/s Noble & Nexus Animal Health Division, 81-A, Street No. 2 (L), Ghalib City, East Canal Road, Faisalabad.
	Detail of Drug Sale License	Name: M/s Noble & Nexus Animal Health Division Address: Plot No. 47,48, Basement Commercial area Ghalib city, near eden garden 208, Chak road, Faisalabad. Validity: **21-08-2027** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Stovek LLC, 2, Zadvorjenskaya St., Room 67, Stolbtsy, 222660 Minsk Region, Republic of Belarus
	Name and address of marketing authorization holder	M/s Stovek LLC, 2, Zadvorjenskaya St., Room 67, Stolbtsy, 222660 Minsk Region, Republic of Belarus
	Name of exporting country	Republic of Belarus
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 25347 Dated 07-09-2022
	Fee including differential fee	Rs : 75,000/- Dated 05-09-2022 (slip No. 09779780)
	Brand Name +Dosage Form + Strength	Triviron Forte-TRV oral solution
	Composition	Each 1ml contains: aRNase (1,5-bis-[N.N-1(4-Tetradecyl) Diazol-1-abicyclo [2.2.2.] octyl] pentane tetrobromide…30mg
	Finished Product Specification	-
	Pharmacological Group	Antiviral
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	-
	International availability	N/A
	Me-too status	N/A

	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 03-17/1197 dated 21-04-2022 issued by Department of Veterinary and Food control of the Ministry of Agriculture and Food of the Republic of Belarus confirms that Triviron Forte- TRV does not contain animal products in its composition and its free sale status in the country of origin. ➢ Original Legalized COPP No. 7328-10-20 issued by Department of Veterinary and Food control of the Ministry of Agriculture and Food of the Republic of Belarus confirms the GMP status of the manufacturer. ➢ Original legalized sole distribution agreement dated 29-10-2021 between M/s Stovek LLC, Republic of Belarus and M/s Noble & Nexus Animal Health Division, Faisalabad.
	Remarks of the Evaluator [XXV]	**Recommended clinical use:** for therapeutic and prophylactic purposes in animals and poultry with infections caused by RNA viruses. **Target species:** Poultry, cattle **Shortcomings:** • Clarification regarding origin/source of the applied product since FSC states "*Triviron Forte- TRV does not contain animal products in its composition"* while in annexure D, the source "Bovine pancreas" is mentioned under specifications. • Justification of storage conditions along with supporting accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Demanded pack size
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Clarification regarding origin/source of the applied product since FSC states "*Triviron Forte- TRV does not contain animal products in its composition"* while in annexure D, the source "Bovine pancreas" is mentioned under specifications.** • **Justification of storage conditions along with supporting accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.** • **Details regarding pharmacodynamics and pharmacokinetics in addition to its use in food producing animals** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Demanded pack size**	
1432.	Name and address of Applicant	M/s Ubaidullah Enterprises, 45 GC, Shah Rukn-e-Alam Colony, Multan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Shijiazhuang ZDHD Stock-Raising Co. Ltd. No.1, Yinhai Road, Xingtai Weixian County, Industrial District, Xintai City, Hebai Province, China
	Name and address of marketing authorization holder	M/s Shijiazhuang ZDHD Stock-Raising Co. Ltd. No.1, Yinhai Road, Xingtai Weixian County, Industrial District, Xintai City, Hebai Province, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 22987 Dated 15-08-2022
	Fee including differential fee	Rs : 75,000/- Dated 12-08-2022 (slip No. 883274870)

	Brand Name +Dosage Form + Strength	Bromo Forte Oral Solution
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol……..40mg
	Finished Product Specification	Inhouse
	Pharmacological Group	expectorant
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1L, 5L
	International availability	N/A
	Me-too status	Bro Mol-60 Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118536)
	Detail of certificates attached	➢ Scanned copy of legalized Free Sale Certificate No. 221100B0/022469 issued by Bureau of Animal Husbandry & Veterinary of Hebei Province, China confirms free sale status of the applied product in China. Date of issuance: 16-04-2022 validity: 15-04-2025 **(Original certificate is submitted in H&OTC Lyso immune dossier)** ➢ Copy of GMP certificate No. 03006 dated 19-02-2021 valid till 31-05-2022, **expired even upon submission**
	Remarks of the Evaluator [XXV]	06 month accelerated and 36 months long term stability studies data of three batches as per zone-IV-A conditions has been provided. **Shortcomings:** • Copy of valid **DSL,** since the firm has submitted copy of provisional certificate for enlistment as importer (Form-6) • Original legalized valid relevant GMP of the manufacturer abroad. • Original notarized exclusive distribution agreement/ letter of authorization.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original legalized valid Free Sale Certificate** • **Original legalized valid relevant GMP of the manufacturer abroad.** • **Original notarized exclusive distribution agreement/ letter of authorization.**	

b. Deferred cases (Veterinary)

1433.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Osmosis Nutrition Sdn. Bhd., 16014, Jalan Nilam 3, Bandar Nilai Utama, 71800 Nilai, Negeri Sembilan, Malaysia
	Name and address of marketing authorization holder	M/s Osmosis Nutrition Sdn. Bhd., 16014, Jalan Nilam 3, Bandar Nilai Utama, 71800 Nilai, Negeri Sembilan, Malaysia
	Name of exporting country	Malaysia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 16318 Dated 08-07-2020
	Fee including differential fee	Rs : 100,000 Dated 08-07-2020

	Brand Name +Dosage Form + Strength	Lincocen 44 Premix Powder
	Composition	Each gram contains: Lincomycin Hydrochloride eq. to Lincomycin…44mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	1Kg, 5Kg, 10Kg, 25Kg
	International availability	N/A
	Me-too status	Could not be confirmed in the applied strength
	Detail of certificates attached	➢ Original Legalized COPP No. 0564HA/2018 dated 21-08-2018 issued by Drug Control Authority National Pharmaceutical Regulatory Division (NPRA), Ministry of Health Malaysia confirms GMP status of the manufacturer but **DOES NOT CONFIRM** free sale status of the product in the exporting country. Validity: 2 Years ➢ Original Legalized GMP certificate No. 793/18 issued on 02-08-2018 is **valid upon submission but expired now.** ➢ Original Legalized power of attorney dated 06-09-2018 to the applicant for the applied product.
	Remarks of the Evaluator	**Shortcomings:** • Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country • Provide Original legalized valid COPP and GMP certificate since the already submitted original COPP and GMP certificate **are expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following • Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country • Original legalized valid COPP and GMP certificates • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. ➢ Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: ➢ Original legalized COPP No. 0574H/2023 dated 28-11-2023 issued by Pharmaceutical services programme Ministry of Health Malaysia, **confirms the free sale status** of the product in the country of origin and GMP status of the manufacturer. ➢ **Metoo status:** Linco Grow 44 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 118650) ➢ 06 months accelerated and 24-months real time stability studies data of three batches as per zone IV-A conditions. ➢ Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Decision: Approved subject to compliance to current import policy for finished drugs.	

1434.	Name and address of Applicant	M/s Aves Care, Office Address: P-74, Street No. 3, Rehman town, Satiana Road, Faisalabad. Warehouse Address: P-68, Street No. 3, Rehman Town, Satiana Road, Faisalabad, Pakistan
	Detail of Drug Sale License	**Not Provided**
	Name and address of manufacturer	M/s Cenavisa S.L. Cami Pedra Estela, s/n 43205 Reus, Spain
	Name and address of marketing authorization holder	M/s Cenavisa S.L. Cami Pedra Estela, s/n 43205 Reus, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24717 Dated 07-09-2021
	Fee including differential fee	Rs : 1,50,000 Dated 02-09-2021 (slip No. 9111732823)
	Brand Name +Dosage Form + Strength	Doxycen 500 powder
	Composition	Each gram contains: Doxycycline (Hyclate)…500mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm, 2000gm
	International availability	N/A
	Me-too status	Farmadox 50 Oral Powder of M/s. ZS Biotech, Lahore. (Reg. No. 113635)
	Detail of certificates attached	➢ Original legalized Certificate of Pharmaceutical Product Certificate No. 2021/272 Issued on 25-03-2021, Certified by Spanish agency of Medicines and Medical Devices, Spain. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturer. ➢ Sole agency certificate between MAH and the applicant is **not provided.**
	Remarks of the Evaluator	Provided 06 months accelerated and 24 months real time stability study data of 03 batches according to zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions is missing. Submit label in accordance with The Drugs (Labelling and Packing) Rules, 1986.
	Decision of 330th meeting: Deferred for following: ➢ Provide copy of valid DSL ➢ notarized original valid Letter of Authorization/ Sole agency certificate. ➢ label in accordance with The Drugs (Labelling and Packing) Rules, 1986 ➢ The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the reply dated 20-09-2023 ➢ copy of DSL valid till 25-10-2023 ➢ Distribution agreement dated 04-09-2023 **attested by notary public Islamabad.**	

	Shortcomings: ➢ label in accordance with The Drugs (Labelling and Packing) Rules, 1986	
	Decision of 331st meeting: Deferred for following: • copy of valid DSL • original valid Letter of Authorization/ Sole agency certificate notarized from country of origin. • label in accordance with The Drugs (Labelling and Packing) Rules, 1986	
	Updated status: The firm has submitted the following: • copy of DSL valid till **25-10-2028** • original legalized Letter of Authorization/ power of attorney valid for 5 years. • label in accordance with The Drugs (Labelling and Packing) Rules, 1986	
	Decision: Approved subject to compliance to current import policy for finished drugs.	
1435.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland
	Name and address of marketing authorization holder	M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1681 Dated 13-01-2021
	Fee including differential fee	**Rs : 50,000** Dated 13-01-2021
	Brand Name +Dosage Form + Strength	Multimin 90 Solution for injection for cattles
	Composition	Each ml contains: Zinc Eq. to 74.68mg of Zinc Oxide…60mg Manganese Eq. to 20.92mg of Manganese Carbonate…10mg Copper Eq. to 26.09mg of Copper Carbonate…15mg Selenium Eq. to 10.95mg of Sodium Selenite…5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Mineral supplement
	Shelf life	30 months
	Demanded Price	Decontrolled
	Pack size	100ml and 500ml
	International availability	**Ireland approved**
	Me-too status	N/A
	Detail of certificates attached	➢ Copy of Free sale certificate No. FSC-19-0029 dated 19-11-2019 issued by Health Products Regulatory Authority (HPRA), Ireland. ➢ Copy of GMP certificate No. 21196/V10956 dated 11-05-2018 issued by Health Products Regulatory Authority (HPRA), Ireland. ➢ Copy of Letter of Authorization (LoA) dated 06-03-2020 provided Validity: July 01, 2022.
	Remarks of the Evaluator	Provided 06 months accelerated and **only 24 months** long term stability studies data as per zone-IV-A conditions **Shortcomings:**

		• Provide original legalized valid Power of attorney/sole agency certificate since the already submitted copy is **expired now but valid upon submission** • Provide original legalized valid GMP certificate of the manufacturer abroad since more than 3 years have elapsed since the date of inspection. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **100ml and 500ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Revised form 5A stating correct name and address of manufacturer abroad (including contract manufacturers, if any) since ***M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland*** is written on form-5A while copy of GMP certificate of ***M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland*** is provided
	Decision of 329th meeting: Deferred for following: • Original legalized valid Power of attorney/sole agency certificate since the already submitted copy is expired now but valid upon submission • Original legalized valid GMP certificate of the manufacturer abroad since more than 3 years have elapsed since the date of inspection. • Choice of only one pack size • Revised form 5A stating correct name and address of manufacturer abroad (including contract manufacturers, if any) since *M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland* is written on form-5A while copy of GMP certificate of *M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland* • Complete real time stability studies data, upto claimed shelf life, of three batches at zone IV-A conditions. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the reply dated 31-08-2023, 22-02-2024 and 28-03-2024 ➢ Original notarized authorization letter dated 18-01-2024 for Multimin Solution for injection for cattle, valid for 5 years ➢ Copy of EUDRA GMP certificate of both bulk manufacturer and finished product manufacturers ➢ Revised form 5A stating following details: **Product License Holder:** Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland **Bulk Manufacturer:** Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland **Finished product Manufacturer:** Laboratoires Biove, 3 Rue de Lorraine Arques, 62510 France • 30-month real time stability studies data, of three batches as per zone IV-A conditions. **Shortcomings:** ➢ Choice of only one pack size.	
	Decision: Approved subject to compliance to current import policy for finished drugs. Firm shall submit choice of only one pack size before issuance of registration letter.	
1436.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation,

		Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17946 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Megasil LA Suspension for Injection
	Composition	Each ml Contains: Amoxicillin as (Trihydrate)…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Amocillin 15% Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.113596)
	Detail of certificates attached	▪ Originally legalized COPP No. 26.09.2008-20/0057 dated 17-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 25-09-2023** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** ➢ Provide original legalized valid relevant GMP certificate since the already submitted **is expired now but valid upon submission.** ➢ Confirmation of **dedicated penicillin manufacturing facility.**
	Decision of 330th meeting: Deferred for following: • original legalized valid relevant GMP certificate • confirmation of dedicated penicillin manufacturing facility.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the reply dated 12-10-2023 and 24-01-2024 Copy of legalized valid GMP certificate having scope of penicillin sterile liquid preparations	
	Decision: Approved subject to compliance to current import policy for finished drugs.	
1437.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	Name: M/s Brand Station, Address: 69 Wocland villas Lahore, near Raiwind road, Lahore. Validity: 10-08-2027 Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam
	Name and address of marketing authorization holder	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam North Star Import Export Joint Stock Company, 69 Hung Vuong Road, Thoi Binh Ward, Ninh Kieu District, cantho City, Vietnam. (supplier)
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 10388 Dated 23-04-2022
	Fee including differential fee	Rs: 150,000 Dated 23-04-2022 (slip N0. 1848650184)
	Brand Name +Dosage Form + Strength	Tylosin 10% Premix
	Composition	Each gram contains: Tylosin as Tylosin Tartrate…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	5gm, 10gm, 20gm, 30gm, 50gm, 100gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm aluminum coated PE bags; 5gm, 10gm, 20gm, 30gm, 50gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm aluminum coated plastic can
	International availability	N/A
	Me-too status	Tylo Tartrate-100 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113430)
	Detail of certificates attached	• Original legalized FSC No.1223/2021/QLT-CFS dated **30-11-2021** issued by the Ministry of Agriculture and Rural Development, Department of Animal Health, Vietnam Validity: 2 years • Original legalized GMP certificate No. 14/22/GCN-GMP dated 28-04-2022 issued by the Ministry of Agriculture and Rural Development Socialistic Republic of Vietnam valid for 5 years. • Originally legalized sole distribution agreement No. TNSBS-SC-200521 dated 20-05-2021

	Remarks of the Evaluator	Firm has provided 06-month accelerated (40±2ºC/ 75±5%) and 36-month real time (30±2ºC/ 65±5%) stability studies data of three batches. **Shortcomings:** • original legalized valid FSC since the already submitted is expired now but valid upon submission. ➢ Label claim mentioned on the submitted label states Tylosin Phosphate 100mg/gram while the applied product is Tylosin as Tartrate…100mg/gram. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ Clarification regarding the applied formulation since Tylosin Phosphate 100mg/gram is mentioned on label while Tylosin as Tartrate…100mg/gram is mentioned on Form-5A.
	Decision of 331st meeting: Deferred for following: • original legalized valid FSC since the already submitted is expired now but valid upon submission. • Label claim mentioned on the submitted label states Tylosin Phosphate 100mg/gram while the applied product is Tylosin as Tartrate…100mg/gram. Submit label in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Clarification regarding the applied formulation since Tylosin Phosphate 100mg/gram is mentioned on label while Tylosin as Tartrate…100mg/gram is mentioned on Form-5A.	
	Updated status: The firm has submitted the following: • original legalized FSC No.1065/2023/QLT-CFS dated 05-10-2023 issued by the Ministry of Agriculture and Rural Development, Department of Animal Health, Vietnam Validity: 2 years • Label in accordance with The Drugs (Labelling and Packing) Rules, 1986 mentioning salt form Tylosin tartrate.	
	Decision: Approved subject to compliance to current import policy for finished drugs.	
1438.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	Name: M/s Brand Station, Address: 69 Wocland villas Lahore, near Raiwind road, Lahore. Validity: 10-08-2027 Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam
	Name and address of marketing authorization holder	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam North Star Import Export Joint Stock Company, 69 Hung Vuong Road, Thoi Binh Ward, Ninh Kieu District, cantho City, Vietnam. (supplier)
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 10616 Dated 26-04-2022
	Fee including differential fee	Rs: 150,000 Dated 26-04-2022 (slip N0. 91227211)
	Brand Name +Dosage Form + Strength	Tylofos Oral Solution
	Composition	Each ml contains: Fosfomycin Sodium…25mg Tylosin Tartrate…25mg

	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	1000ml, 500ml bottles
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized FSC No.1415/2020/QLT-CFS dated **23-11-2020** issued by the Ministry of Agriculture and Rural Development, Department of Animal Health, Vietnam Validity: 2 years Original legalized GMP certificate No. 14/22/GCN-GMP dated 28-04-2022 issued by the Ministry of Agriculture and Rural Development Socialistic Republic of Vietnam valid for 5 years. Originally legalized sole distribution agreement No. TNSBS-SC-200521 dated 20-05-2021
	Remarks of the Evaluator	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 36-month real time (30±2ºC/ 65±5%RH) stability studies data of three batches. **Shortcomings:** original legalized valid FSC since the already submitted is expired now but valid upon submission. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 331st meeting: Deferred for following: • original legalized valid FSC • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • original legalized FSC No.88/2023/QLT-CFS dated 09-01-2023 issued by the Ministry of Agriculture and Rural Development, Department of Animal Health, Vietnam Validity: 2 years **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or availability of the said formulation in any reference country or PICs member country or ML-4 country.	
1439.	Name and address of Applicant	M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	**Valid copy required**
	Name and address of manufacturer	M/s Boehringer Ingelheim Animal Health France, 4 Chemin du Calquet, 31000, Toulouse, France
	Name and address of marketing authorization holder	M/s Boehringer Ingelheim Vetmedica GmbH, Binger Straβe 173, 55216 Ingelheim am Rhein, Germany
	Name of exporting country	France
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 7341 Dated 15-03-2022
	Fee including differential fee	Rs : 75,000 Dated 20-02-2022 (slip No. 5332165938)
	Brand Name +Dosage Form + Strength	Cymelarsan Lyophilisate for Solution for Injection

	Composition	Each vial contains: Melarsomine Dihydrochloride…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Parasiticide product
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	20ml vial
	International availability	**Not provided**
	Me-too status	**Not available**
	Detail of certificates attached	➢ Original Legalized COPP No. 21-295648 dated 28-06-2021 issued by Anses- Agence nationale du medicament veterinaire France confirms GMP status of the manufacturer but **DOES NOT CONFIRM** free sale status of the product in the exporting country. ➢ Original Legalized GMP certificate No. 21-289989 dated 13-04-2021 issued by Anses- Agence nationale du medicament veterinaire France**.** Original Legalized letter of authorization dated 27-10-2021 to the applicant for the applied product.
	Remarks of the Evaluator	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 36-month real time (30±2ºC/ 65±5%RH**)** stability studies data of three batches. **Shortcomings:** • copy of valid DSL • Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country • Evidence of approval of applied formulation in reference regulatory authorities/agencies.
	Decision of 331st meeting: Registration Board deferred for availability of the said formulation in the country of origin or any reference country or PICs member country or ML-4 country.	
	Updated status: M/s Saadat International has informed that our principal company Boehringer Ingelheim has decided to **withdraw the application** for the registration of imported drug CYMELARSAN. The firm has also submitted copy of withdrawal letter dated 22-04-2024 stating that "the reason of withdrawal is due to the business decision to focus on Avian products for the time being. In case the business decision will change, we will proceed with new submission of up to date file with the new fee."	
	Decision: Registration Board acceded to the firm's request and declared the application as disposed of/rejected.	
1440.	Name and address of Applicant	M/s Lucky Core Industries Limited, 5 West Wharf Road Karachi (Formerly M/s ICI Pakistan Limited)
	Detail of Drug Sale License	Name: M/s Lucky Core Industries Limited Address: 5 West Wharf Road, Karachi. Validity: **10-03-2026** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s CKL Africa Ltd., Mashiara Park, Kaptagat Road, off Waiyaki Way, P.O Box 40596-00100 Nairobi, Kenya
	Name and address of marketing authorization holder	M/s Intervet South Africa (Pty) Ltd., 20 Spartan Road, Spartan South Africa
	Name of exporting country	Kenya
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 10598 Dated 27-04-2022
	Fee including differential fee	Rs: 75,000 Dated 27-04-2022 (slip N0. 54176714746)

	Brand Name +Dosage Form + Strength	Taktic Stock Spray 12.5%
	Composition	Each unit contains: Amitraz…12.5% w/v
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticide
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20ml, 40ml, 100ml
	International availability	Could not be confirmed in the applied strength
	Me-too status	Frazal Spray of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109276)
	Detail of certificates attached	➢ Originally legalized COPP dated 04-04-2022 certified by Veterinary Medicine Directorate, Nairobi confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate No. GMP 0009 dated 22.03.2021 certified by Veterinary Medicine Directorate, Nairobi. Validity: 05-03-2023 ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator	➢ Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. ➢ The firm has submitted revised form-5A with its new title along with fee Rs. 75,000/- (slip No.37338164827 and 4585052511) for change of title of the firm. **Target species:** Cattle, sheep, goats, camels and dogs **Shortcomings:** • Provide valid legalized original GMP certificate, since the already submitted **copy is expired now but valid upon submission.** • Provide valid legalized original letter of authorization (LOA)/ distribution agreement. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • valid legalized original letter of authorization (LOA)/ distribution agreement. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Differential fee Rs.75,000/- for registration of generic drug.	
	Updated status: The firm has submitted the following: ➢ Original notarized letter of authorization (LOA) dated 23-01-2024 • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Differential fee Rs. 225,000/- for registration of generic drug vide slip no. 9531094103	
	Decision: Approved subject to compliance to current import policy for finished drugs.	
1441.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).

	Name and address of manufacturer	M/s Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name and address of marketing authorization holder	M/s Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24962 Dated 24-09-2020
	Fee including differential fee	**Rs : 50,000** Dated 23-09-2020
	Brand Name +Dosage Form + Strength	Falvopak 80 Premix
	Composition	Each Kg contains: Bambermycin…80gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 201100B0/022161 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 31-03-2020 ➢ Original Legalized GMP Certificate No. (2019) GMP13004 issued by Fujian Province Department of Agriculture and Rural Affairs Date of issuance: 02-09-2020 Validity: 01-09-2024 ➢ Original Legalized Power of Attorney dated 31-03-2020 for the applied product
	Remarks of the Evaluator	**Shortcomings:** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Differential fee Rs. 50,000/- for registration of generic drug product. • Provide long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.
	Decision of 326th meeting: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Differential fee Rs. 50,000/- for registration of generic drug product. • Long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.	
	Updated status: The firm has submitted the following:	

Sr. No.	Observation	Firm's response

		i	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	Flavomycin 80 has been **approved by EU** under authorization number 0022-2444 with date of authorization status 12/06/2023. **Authorized in Bulgaria** Reference: https://medicines.health.europa.eu/veterinary/en/600000098550 accessed dated 31-05-2024
		ii	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Not registered in DRAP
		iii	Differential fee Rs. 50,000/- for registration of generic drug product.	N/A
		iv	Long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.	Submitted
	Decision: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country.			

Case no. 03 Registration applications of drugs for which stability study data is submitted

a. New cases

1442.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 5mg tablet
	Composition	Each film coated tablet contains: Apixaban……..……..5mg
	Diary No. Date of R& I & fee	Dy. No. 36424 dated 05-11-2018, Fee Rs: 20,000/- dated 05-11-2018
	Pharmacological Group	Factor Xa inhibitor, anticoagulant
	Type of Form	Form 5D
	Finished product Specifications	Inovator Specification
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Eliquis 5mg film-coated Tablet by M/s Bristol-Myers Squibb-Pfizer (USFDA Approved)
	Me-too status	Apiban 5mg Tablet of M/s Highnoon Laboratories Ltd. (Reg. No.104682)
	GMP status	GMP certificate dated 14-11-2023 based upon evaluation conducted on 03-04-2023
	Remarks of the Evaluator	
STABILITY STUDY DATA		
Manufacturer of API	M/s CTX Life Sciences Pvt. Ltd	

	Address Block No. 251-252 Sachin Magdalla Road, Gidc, Sachin, Surat, Gujarat, India		
API Lot No.	21AP 000002		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton cardboard boxes		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TAU001	TAU002	TAU003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	04-21	04-21	04-21
Date of Initiation	08-04-2021	21-04-2021	21-04-2021
No. of Batches	03		
Date of Submission	30-11-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch#21AP 000002) of API (Apixaban) from M/s M/s CTX Life Sciences Pvt. Ltd, India and M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36 & 0, 1, 2, 3 & 6 months respectively. Batches: (AB200001, AB200002, AB200003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate no. 22063346 dated 30-05-2022 in the name of M/s CTX Life Sciences Pvt. Ltd Block NO. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat, Gujarat, India issued by Food & Drug Control Administration valid till 29/05/2025
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice Number EI/3002100696, dated 19/02/2021 cleared by AD(I&E) Lahore, dated 03-03-2021.

7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** TAU001 / 2500 tablets / 04-2021 TAU002 / 2500 tablets / 04-2021 TAU003 / 2500 tablets / 04-2021
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed against Apiban 5mg tablet (batch No. 202918) of M/s Highnoon Laboratories Ltd., Lahore.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

Sr. No.	Observation	Firm's response
i	Dissolution test parameters are mentioned as 45 minutes sampling time whereas the acceptance limit of innovator product is testing at 30 minutes, Justify.	At the time, when product was manufactured we did not know innovator's product dissolution test parameters. So we followed FDA dissolution test parameters that are mentioned as 45minutes sampling time but our results were more than 85% after 30 minutes. Now we revised FPP dissolution test parameters as per innovator's product where the acceptance limit of testing is at 30 minutes.

Decision: Registration Board approved registration of Apiban 5mg tablet with Innovator's specifications by M/s Wimits Pharmaceuticals (Pvt) Ltd. Raiwind Road, Lahore.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1443.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 2.5mg tablet
	Composition	Each film coated tablet contains: Apixaban……....2.5mg
	Diary No. Date of R& I & fee	Dy. No. 36423 dated 05-11-2018, Fee Rs: 20,000/- dated 05-11-2018
	Pharmacological Group	Factor Xa inhibitor, anticoagulant
	Type of Form	Form 5D
	Finished product Specifications	Inovator Specification
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO

	Approval status of product in Reference Regulator Authorities	Eliquis 2.5mg film-coated Tablet by M/s Bristol-Myers Squibb-Pfizer (USFDA Approved)
	Me-too status	Apiban 2.5mg Tablet of M/s Highnoon Laboratories Ltd. (Reg. No. 104681)
	GMP status	GMP certificate dated 14-11-2023 based upon evaluation conducted on 03-04-23
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Life Sciences Pvt. Ltd **Address** Block No. 251-252 Sachin Magdalla Road, Gidc, Sachin, Surat, Gujarat, India		
API Lot No.	21AP 000002		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton cardboard boxes		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TAH001	TAH002	TAH003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	04-21	04-21	04-21
Date of Initiation	08-04-2021	30-04-2021	30-04-2021
No. of Batches	03		
Date of Submission	30-11-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch#21AP 000002) of API (Apixaban) from M/s M/s CTX Life Sciences Pvt. Ltd, India and M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36 & 0, 1, 2, 3 & 6 months respectively. Batches: (AB200001, AB200002, AB200003)

<table>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate no. 22063346 dated 30-05-2022 in the name of M/s CTX Life Sciences Pvt. Ltd Block NO. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat, Gujarat, India issued by Food & Drug Control Administration valid till 29/05/2025</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Invoice Number EI/3002100696, dated 19/02/2021 cleared by AD(I&E) Lahore, dated 03-03-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TAH001</td><td>2500 tablets</td><td>04-2021</td></tr>
<tr><td>TAH002</td><td>2500 tablets</td><td>04-2021</td></tr>
<tr><td>TAH003</td><td>2500 tablets</td><td>04-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Apiban 2.5mg tablet (batch No. 202892) of M/s Highnoon Laboratories Ltd., Lahore.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR
<table>
<tr><th>Sr. No.</th><th>Observation</th><th>Firm’s response</th></tr>
<tr><td>i</td><td>Dissolution test parameters are mentioned as 45 minutes sampling time whereas the acceptance limit of innovator product is testing at 30 minutes, Justify.</td><td>At the time, when product was manufactured we did not know innovator’s product dissolution test parameters. So we followed FDA dissolution test parameters that are mentioned as 45minutes sampling time but our results were more than 85% after 30 minutes. Now we revised FPP dissolution test parameters as per innovator’s product where the acceptance limit of testing is at 30 minutes.</td></tr>
</table></td></tr>
<tr><td colspan="3">Decision: Registration Board approved registration of Apiban 2.5mg tablet with Innovator’s specifications by M/s Wimits Pharmaceuticals (Pvt) Ltd. Raiwind Road, Lahore.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

b. Deferred cases

1444.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila.

	Brand Name +Dosage Form + Strength	Wenopaa 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.14187 dated 07-03-2019; Fee Rs: 20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China.		
API Lot No.	20190907		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-004	T-004	T-004
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	22-07-2020	22-07-2020	22-07-2020
No. of Batches	03		
Date of Submission	14-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 20190907) of API from M/s Huainan Shunlong Pharmaceutical

		Co., Ltd., China and M/s Wenovo Pharmaceuticals, Taxila are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	**Not provided**
4.	Stability study data of API from API manufacturer	**Not provided**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 29-09-2018 in the name of M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China issued by Anhui Food and Drug Administration Anhui Pharmaceutical Profession Association China. Valid till 28-09-2023. The submitted copy of GMP certificate **could not be verified.**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not provided**
7.	Protocols followed for conduction of stability study	**Not provided**
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	The same formulation ingredients are selected which are used by the innovator Jardiance 10mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.
10.	Complete batch manufacturing record of three stability batches.	**Not provided**
11.	Record of comparative dissolution data (where applicable)	**Not Provided**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided**

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer

- Submit stability study data of API from API manufacturer as per zone IV-A conditions.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Dissolution test parameters are mentioned as 30 minutes sampling time whereas the acceptance limit of innovator product is testing at 15 minutes. Justify.
- Dissolution test is performed on five (5) sample units at each time point, whereas as per USP Dissolution general chapter 6 or 12 units should be tested, justify.
- Record of comparative dissolution data
- Justification for using overage in master formula.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted revised stability data along with chromatograms and digital data logger vide Dy. No. 5159 dated 20-05-2024.

Decision: Registration Board approved registration of Wenopaa 10mg Tablet with Innovator's specifications by Wenovo Pharmaceuticals, Taxila. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Registration letter shall be issued after submission of following:

- **Method used for analysis of API from API Manufacturer**
- **Stability study data of API from API manufacturer**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Documents/evidence for the procurement of API.**
- **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**

1445.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Wenopaa 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy. No.14188 dated 07-03-2019; Fee Rs: 20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China.		
API Lot No.	20190907		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-007	T-008	T-009
Batch Size	2300 tablets	2300 tablets	2300 tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	22-07-2020	22-07-2020	22-07-2020
No. of Batches	03		
Date of Submission	14-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 20190907) of API from M/s Huainan Shunlong Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals, Taxila are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	**Not provided**
4.	Stability study data of API from API manufacturer	**Not provided**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 29-09-2018 in the name of M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China issued by Anhui Food and Drug Administration Anhui Pharmaceutical Profession Association China. Valid till 28-09-2023. The submitted copy of GMP certificate **could not be verified.**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not provided**
7.	Protocols followed for conduction of stability study	**Not provided**
8.	Method used for analysis of FPP	Submitted

9.	Drug-excipients compatibility studies (where applicable)	The same formulation ingredients are selected which are used by the innovator Jardiance 25mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.
10.	Complete batch manufacturing record of three stability batches.	**Not provided**
11.	Record of comparative dissolution data (where applicable)	**Not Provided**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided**

REMARKS OF EVALUATOR[x]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit stability study data of API from API manufacturer as per zone IV-A conditions.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Dissolution test parameters are mentioned as 30 minutes sampling time whereas the acceptance limit of innovator product is testing at 15 minutes. Justify.
- Dissolution test is performed on five (5) sample units at each time point, whereas as per USP Dissolution general chapter 6 or 12 units should be tested, justify.
- Record of comparative dissolution data
- Justification for using overage in master formula.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status:

The firm has submitted revised stability data along with chromatograms and digital data logger vide Dy. No. 5160 dated 20-05-2024.

Decision: Registration Board approved registration of Wenopaa 25mg Tablet with Innovator's specifications by Wenovo Pharmaceuticals, Taxila. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Registration letter shall be issued after submission of following:

- **Method used for analysis of API from API Manufacturer**
- **Stability study data of API from API manufacturer**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Documents/evidence for the procurement of API**
- **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**

1446.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Apixacol 5 mg Tablets
	Composition	Each Film Coated Tablet Contains: Apixaban…….5 mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16136 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Anticoagulant (selective direct factor Xa inhibitor)
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	ELIQUIS (apixaban) tablets USFDA approved
	Me-too status	NA
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	(Apixaban) M/s CHANGZHOU PHARMACEUTICAL FACTORY; Address: No.518, Laodong East Road, Changzhou, Jiangsu Province, PR China.		
API Lot No.	Apixaban: ZSAP200101		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	AZT-PB-01	AZT-PB-02	AZT-PB-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	26-06-2020	26-06-2020	26-06-2020
No. of Batches	03		
Date of Submission	15-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 312th meeting dated 29, January 2021, decided to approve registration of Gencox 90mgTablets(Etoricoxib) . Inspection date: 31-12-2020 & 11-01-2021. The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC QC-EQ-003 for Gencox 90 mg tablets which were 21 CFR compliant for initial 6 months. Adequate monitoring and control were available for stability chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# ZSAP200101) of API (Apixaban) from No.518, Laodong East Road, Changzhou, Jiangsu Province, and PR China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura -Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no. 20160138 issued by Jiangsu Food and Drug Administration valid until 24-09-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CY119238B dated MAR.06, 2020 from exporter M/s Changzhou Pharmaceutical Factory, No.518, Laodong East Road, Changzhou, Jiangsu 213018, China, for import of 33 grams of Apixaban (Batch No. ZSAP200101) in name of M/s McOlson Research Labs. (Pvt) Ltd Lahore attested by AD (I&E) DRAP Lahore dated 11-03-2020.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>AZT-PB-01</td><td>1000 tablets</td><td>06-2020</td></tr><tr><td>AZT-PB-02</td><td>1000 tablets</td><td>06-2020</td></tr><tr><td>AZT-PB-03</td><td>1000 tablets</td><td>06-2020</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Eliquis tablets (5mg) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) , Phosphate buffer (pH 6.8) & phosphate buffer 6.8 with 0.05% SLS</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
<u>Shortcomings:</u>
Latest GMP inspection report conducted within period of 3 years.
Justification shall be submitted for not including test of “Uniformity of Dosage Unit” by way of “content Uniformity” in finished drug product specifications.
Justify the use of SLS in dissolution medium for performance of CDP studies of 5mg strength</td></tr>
<tr><td colspan="3">Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.</td></tr>
<tr><td colspan="3">Updated status: The firm has submitted the following:<table><tr><th>Sr. No.</th><th>Observations</th><th>Firm’s response</th></tr><tr><td>i</td><td>Latest GMP inspection report conducted within period of 3 years.</td><td>GMP inspection certificate dated 29-11-2022 based on evaluation conducted on 04-06-2022</td></tr><tr><td>ii</td><td>Justification shall be submitted for not including test of “Uniformity of Dosage Unit” by way of “content Uniformity” in finished drug product specifications.</td><td>We have performed the “Uniformity of dosage unit” by way of “content uniformity”. It is included in finished product specifications. Copies of finished product specifications, related SOP and finished product analysis report for all stability batches are attached.</td></tr><tr><td>iii</td><td>Justify the use of SLS in dissolution medium for performance of CDP studies of 5mg strength</td><td>We used the same medium for dissolution testing as mentioned in USFDA data base which includes SLS.</td></tr></table></td></tr>
<tr><td colspan="3">Decision: Registration Board approved registration of Apixacol 5mg tablet with Innovator’s specifications by M/s McOlson Research Labs. (Pvt) Ltd. Sheikhpura.
Registration letter shall be issued after Fee verification as per procedure adopted by Registration Board.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

1447.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Apixacol 2.5 mg Tablets
	Composition	Each Film Coated Tablet Contains: Apixaban…….2.5 mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16137 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Anticoagulant (selective direct factor Xa inhibitor)
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	ELIQUIS (apixaban) tablets Initial U.S (FDA). Approval: 2012
	Me-too status	NA
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s CHANGZHOU PHARMACEUTICAL FACTORY; Address: No.518, Laodong East Road, Changzhou, Jiangsu Province, PR China.		
API Lot No.	Apixaban: ZSAP200101		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	AXT-PB-01	AXT-PB-02	AXT-PB-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	26-06-2020	26-06-2020	26-06-2020
No. of Batches	03		
Date of Submission	15-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 312th meeting dated 29,

<table>
<tr><td></td><td></td><td>January 2021, decided to approve registration of Gencox 90mgTablets(Etoricoxib) .
Inspection date: 31-12-2020 & 11-01-2021.
The report shows that:
• Finished Pharmaceutical Product stability testing was conducted on HPLC QC-EQ-003 for Gencox 90 mg tablets which were 21 CFR compliant for initial 6 months.
Adequate monitoring and control were available for stability chamber.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch# ZSAP200101) of API (Apixaban) from No.518, Laodong East Road, Changzhou, Jiangsu Province, and PR China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura -Pakistan are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months.</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of DML no. 20160138 issued by Jiangsu Food and Drug Administration valid until 24-09-2025.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. CY119238B dated MAR.06, 2020 from exporter M/s Changzhou Pharmaceutical Factory, No.518, Laodong East Road, Changzhou, Jiangsu 213018, China, for import of 33 grams of Apixaban (Batch No. ZSAP200101) in name of M/s McOlson Research Labs. (Pvt) Ltd Lahore attested by AD (I&E) DRAP Lahore dated 11-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>AXT-PB-01</td><td>1000 tablets</td><td>06-2020</td></tr>
<tr><td>AXT-PB-02</td><td>1000 tablets</td><td>06-2020</td></tr>
<tr><td>AXT-PB-03</td><td>1000 tablets</td><td>06-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not Provided</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
</table>

13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit Comparative dissolution profile for 2.5mg strength against innovator/reference product.
- Justification shall be submitted for not including test of "Uniformity of Dosage Unit" by way of "content Uniformity" in finished drug product specifications.

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted the following:

Sr. No.	Observations	Firm's response
i	Latest GMP inspection report conducted within period of 3 years.	GMP inspection certificate dated 29-11-2022 based on evaluation conducted on 04-06-2022
ii	Submit Comparative dissolution profile for 2.5mg strength against innovator/reference product.	Submitted Comparative dissolution was performed against Apiban 2.5mg tablet of M/s Highnoon Laboratories in 0.1N HCl pH (1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) & Phosphate buffer (pH 6.8) with 0.05% SLS
iii	Justification shall be submitted for not including test of "Uniformity of Dosage Unit" by way of "content Uniformity" in finished drug product specifications.	We have performed the "Uniformity of dosage unit" by way of "content uniformity". It is included in finished product specifications. Copies of finished product specifications, related SOP and finished product analysis report for all stability batches are attached.

Decision: Registration Board approved registration of Apixacol 2.5mg tablet with Innovator's specifications by M/s McOlson Research Labs. (Pvt) Ltd. Sheikhpura.
Registration letter shall be issued after Fee verification as per procedure adopted by Registration Board.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1448.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot 10 & 25 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Emaxy 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin……. 10 mg
	Diary No. Date of R& I & fee	Dy. No.36799 dated 06-11-2018, Fee Rs: 20,000/- dated 17-10-2018 vide deposit slip No.0742421.
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; As per SRO

	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India.		
API Lot No.	08964005-EMP		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	054DS06	054DS05	054DS04
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	20-05-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 08964005-EMP) of API from M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India and M/s Aspin Pharma (Pvt.) Ltd. Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(EM-001, EM-002, EM-003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/22033183 in the name of M/s Century Pharmaceuticals Limited, Panchmahal, India issued by

		Food and Drug Control Administration, Gujrat state. valid till 10-03-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CPLEXP1800165 dated 10-12-2018 from exporter M/s Century Pharmaceuticals Limited, India, for import of 1.5Kg of Empagliflozin (Batch No. 08964005-EMP) in name of M/s OBS Pakistan (Pvt) Ltd, Karachi attested by AD (I&E) DRAP Karachi dated 11-01-2019. Moreover, the firm has also submitted approval letter dated 28-02-2019 for transfer of API for R&D activities from OBS Pakistan Pvt. Ltd., to Aspin Pharma Pvt. Ltd., issued by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not Submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide Drug-excipients compatibility studies.
- Provide complete batch manufacturing record of three stability batches.
- Provide record of comparative dissolution data.
- Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.
- In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted the following:

Sr. No.	Observations	Firm's response
i	Latest GMP inspection report conducted within period of 3 years.	GMP inspection report dated 13-06-2022 recommends good GMP compliance.
ii	Provide reference of previous approval of applications with stability study data of the firm.	N/A
iii	Provide Drug-excipients compatibility studies.	N/A
iv	Provide complete batch manufacturing record of three stability batches.	Submitted
v	Provide record of comparative dissolution data.	Provided Comparative dissolution was performed against Jardiance tablet (10mg) Batch No. 23C1344 in HCl pH (1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
vi	Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.	Submitted
vii	In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.	As per FDA guidelines for Dissolution Testing for immediate release solid oral dosage form, approaches for setting Dissolution specification for a New Chemical Entity, Dissolution testing should be carried out under mild test condition. For highly soluble and rapidly dissolving drug products (BCS Class 1 & 3), a single-point dissolution test specification of NLT 85% (Q = 85%) in 60 minutes or less is sufficient as a routine quality control test for batch to batch uniformity. On the other basis of above guideline, dissolution test of our product as well as innovator product performed during Comparative Dissolution profile complies with following parameter. i.e. 75 rpm for 30 minutes for dissolution. Therefore, these parameters were finalized for testing of Empagliflozin 25mg Tablet as well as for Empagliflozin 10mg Tablet.

Decision: Registration Board approved registration of Emaxy 10mg Tablet by M/s Aspin Pharma (Pvt.) Ltd. Karachi.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1449.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot 10 & 25 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Emaxy 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin……. 25 mg

	Diary No. Date of R& I & fee	Dy. No.36800 dated 06-11-2018, Fee Rs: 20,000/- dated 06-11-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India.		
API Lot No.	08964005-EMP		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	062DS07	062DS06	062DS05
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	20-05-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 08964005-EMP) of API from M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India and M/s Aspin Pharma (Pvt.) Ltd. Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for

		60 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(EM-001, EM-002, EM-003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/22033183 in the name of M/s Century Pharmaceuticals Limited, Panchmahal, India issued by Food and Drug Control Administration, Gujrat state. valid till 10-03-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CPLEXP1800165 dated 10-12-2018 from exporter M/s Century Pharmaceuticals Limited, India, for import of 1.5Kg of Empagliflozin (Batch No. 08964005-EMP) in name of M/s OBS Pakistan (Pvt) Ltd, Karachi attested by AD (I&E) DRAP Karachi dated 11-01-2019. Moreover, the firm has also submitted approval letter dated 28-02-2019 for transfer of API for R&D activities from OBS Pakistan Pvt. Ltd., to Aspin Pharma Pvt. Ltd., issued by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not Submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed against Jardiance tablet (25mg) Batch No. 906030 in HCl pH (1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.

- Provide Drug-excipients compatibility studies.
- Provide complete batch manufacturing record of three stability batches.
- Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.
- In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted the following:

Sr. No.	Observations	Firm's response
i	Latest GMP inspection report conducted within period of 3 years.	GMP inspection report dated 13-06-2022 recommends good GMP compliance.
ii	Provide reference of previous approval of applications with stability study data of the firm.	N/A
iii	Provide Drug-excipients compatibility studies.	N/A
iv	Provide complete batch manufacturing record of three stability batches.	Submitted
v	Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.	Submitted
vi	In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.	As per FDA guidelines for Dissolution Testing for immediate release solid oral dosage form, approaches for setting Dissolution specification for a New Chemical Entity, Dissolution testing should be carried out under mild test condition. For highly soluble and rapidly dissolving drug products (BCS Class 1 & 3), a single-point dissolution test specification of NLT 85% (Q = 85%) in 60 minutes or less is sufficient as a routine quality control test for batch to batch uniformity. On the other basis of above guideline, dissolution test of our product as well as innovator product performed during Comparative Dissolution profile complies with following parameter. i.e. 75 rpm for 30 minutes for dissolution. Therefore, these parameters were finalized for testing of Empagliflozin 25mg Tablet as well as for Empagliflozin 10mg Tablet.

Decision: Registration Board approved registration of Emaxy 25mg Tablet by M/s Aspin Pharma (Pvt.) Ltd. Karachi.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1450.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, Industrial Triangle Kahuta Road Islamabad.

	Brand Name +Dosage Form + Strength	Lasogap-D Capsule 30mg
	Composition	Each Capsule Contains: Dexlansoprazole DDR Pellets 22.5% equivalent to Dexlansoprazole.....30mg
	Diary No. Date of R& I & fee	Dy.No 33023 dated 04-10-2018 Rs.20,000/- dated 02-10-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30's
	Approval status of product in Reference Regulator Authorities	Dexilant 30mg capsule USFDA approved
	Me-too status	Dextop 30mg Capsule M/s Searle Pharma
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	DLP451		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 1, 3, 6 (months)		
Batch No.	T-001	T-001	T-001
Batch Size	1260 capsules	1260 capsules	1260 capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	18-12-2019	18-12-2019	18-12-2019
No. of Batches	03		
Date of Submission	16-04-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# DLP451) of API (Dexlansoprazole DD pellets 22.5%) from M/s Vision Pharma, kahuta Road, Islamabad and M/s Glitz Pharma, Islamabad are submitted.

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Method used for analysis of API submitted by API manufacturer only</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Not submitted</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 600621 dated 03-09-2019, for import of 2.0 Kg of Dexlansoprazole DDR 22.5% pellets in name of M/s Glitz Pharma, Islamabad.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Not Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T-001</td><td>1260 capsules</td><td>28-11-2019</td></tr>
<tr><td>T-002</td><td>1260 capsules</td><td>28-11-2019</td></tr>
<tr><td>T-003</td><td>1260 capsules</td><td>28-11-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Dextop capsule (30mg) of M/s The Searle Company Ltd., Karachi Batch No. 054 in 0.1N HCl, Buffer (pH 5.5) & Phosphate buffer (pH 7)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[x]
<u>Shortcomings:</u>
Latest GMP inspection report conducted within period of 3 years.
Submit reference of previous approval of applications with stability study data of the firm
Submit method used for analysis of API from finished product manufacturer also.
6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.
Submit protocol followed for conduction of stability study
Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td></tr>
</table>

- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted the following:

Sr. No.	Observations	Firm's response
i	Latest GMP inspection report conducted within period of 3 years.	GMP certificate dated 10-01-2022 based on evaluation conducted on 17-06-2021
ii	Submit reference of previous approval of applications with stability study data of the firm	N/A
iii	Submit method used for analysis of API from finished product manufacturer also.	Submitted
iv	6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.	It is our mistake that we can't consult and follow guidelines at the time but now, 12 units each of test and reference product are used for CDP. It will take time as we are performing CDP as per guidelines and as soon as we get the whole data we will submit the data of CDP in Evaluation Cell.
v	Submit protocol followed for conduction of stability study	Submitted
vi	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
vii	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Registration Board approved registration of Lasogap-D Capsule 30mg with Innovator's specifications by M/s Glitz Pharma, Islamabad.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Registration letter shall be issued after submission of revised comparative dissolution data as per commitment of the firm

1451.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Lasogap-D Capsule 60mg
	Composition	Each Capsule Contains: Dexlansoprazole DDR Pellets 22.5% equivalent to Dexlansoprazole.....60mg
	Diary No. Date of R& I & fee	Dy.No 33024 dated 04-10-2018 Rs.20,000/- dated 02-10-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30's

	Approval status of product in Reference Regulator Authorities	Dexilant 60mg capsule USFDA approved
	Me-too status	Dextop 60mg Capsule M/s Searle Pharma
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	DLP451		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 1, 3, 6 (months)		
Batch No.	T-001	T-001	T-001
Batch Size	1260 capsules	1260 capsules	1260 capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	30-12-2019	30-12-2019	30-12-2019
No. of Batches	03		
Date of Submission	16-04-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# DLP451) of API (Dexlansoprazole DD pellets 22.5%) from M/s Vision Pharma, kahuta Road, Islamabad and M/s Glitz Pharma, Islamabad are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API submitted by API manufacturer only
4.	Stability study data of API from API manufacturer	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not submitted**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. 600621 dated 03-09-2019, for import of 2.0 Kg of Dexlansoprazole DDR 22.5% pellets in name of M/s Glitz Pharma, Islamabad.

<table>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Not Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T-001</td><td>1260 capsules</td><td>30-11-2019</td></tr>
<tr><td>T-002</td><td>1260 capsules</td><td>30-11-2019</td></tr>
<tr><td>T-003</td><td>1260 capsules</td><td>30-11-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Dextop capsule (60mg) of M/s The Searle Company Ltd., Karachi Batch No. 0034 in 0.1N HCl, Buffer (pH 5.5) & Phosphate buffer (pH 7)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
</table>

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit reference of previous approval of applications with stability study data of the firm
- Submit method used for analysis of API from finished product manufacturer also.
- 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.
- Submit protocol followed for conduction of stability study
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision of 333rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Updated status: The firm has submitted the following:

Sr. No.	Observations	Firm's response
i	Latest GMP inspection report conducted within period of 3 years.	GMP certificate dated 10-01-2022 based on evaluation conducted on 17-06-2021
ii	Submit reference of previous approval of applications with stability study data of the firm	N/A

iii	Submit method used for analysis of API from finished product manufacturer also.	Submitted
iv	6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.	It is our mistake that we can't consult and follow guidelines at the time but now, 12 units each of test and reference product are used for CDP. It wil take time as we are performing CDP as per guidelines and as soon as we get the whole data we will submit the data of CDP in Evaluation Cell.
v	Submit protocol followed for conduction of stability study	Submitted
vi	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
vii	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Registration Board approved registration of Lasogap-D Capsule 60mg with Innovator's specifications by M/s Glitz Pharma, Islamabad.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Registration letter shall be issued after submission of revised comparative dissolution data as per commitment of the firm

Agenda of Deputy Director (PE&R) (Mr. Muneeb Ahmed Cheema)

1452	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt. Ltd.** **14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Section approval letter No. 1-18/92-Lic (Vol-III) dated 27.02.2023 (Soft Gelatin Capsule-General New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	24.10.2023
	Details of fee submitted	PKR 30,000/- Dated 10/10/2023
	The proposed proprietary name / brand name	**D-Cad 3 5000IU Soft Gel Capsule**
	Strength / concentration of drug of Active Pharmaceutical	Each capsule contains: Vitamin D3 (Cholecalciferol)…….…….5000IU

	ingredient (API) per unit	
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Pharmaceutical form of applied drug	Soft Gelatin capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EURO-PHARM INTERNATIONAL CANADA INC https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=85664
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Euro D Capsules 5000IU of Euro Pharma Canada. The details of product are not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China		
API Lot No.	221101		
Description of Pack (Container closure system)	Alu–PVC blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	063NS01	063NS02	063NS03
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	01-04-2023	01-04-2023	01-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Sichuan medical productsAdministration. The certificate specifies that facility is GMP compliant.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 06/03/2023 specifying 1.2000Kg.The invoice is cleared by assistant director I & E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

145	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Section approval letter No. 1-18/92-Lic (Vol-III) dated 27.02.2023 (Soft Gelatin Capsule-General New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	24.10.2023
	Details of fee submitted	PKR 30,000/- Dated 10/10/2023
	The proposed proprietary name / brand name	**D-Cad 3 20000IU Soft Gel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Vitamin D3 (Cholecalciferol)…….…….20000IU
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Pharmaceutical form of applied drug	Soft Gelatin capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	AGES (Austria)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Capsule of Health Aid Vitamin D20000IU Capsules
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China		
API Lot No.	221101		
Description of Pack (Container closure system)	Alu–PVC blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	065NS01	065NS02	065NS03
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	01-04-2023	01-04-2023	01-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Sichuan medical productsAdministration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 06/03/2023 specifying 1.2000Kg.The invoice is cleared by assistant director I & E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
145	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt. Ltd.** **14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Section approval letter No. 1-18/92-Lic (Vol-III) dated 27.02.2023 (Soft Gelatin Capsule-General New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	24.10.2023
	Details of fee submitted	PKR 30,000/- Dated 10/10/2023
	The proposed proprietary name / brand name	**D-Cad 3 50000IU Soft Gel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Vitamin D3 (Cholecalciferol)…….……50000IU

	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Pharmaceutical form of applied drug	Soft Gelatin capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EURO-PHARM INTERNATIONAL CANADA INC https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=85664
	For generic drugs (me-too status)	No available
	Name and address of API manufacturer.	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Euro D 50000 IU softgel capsule, manufactured by EURO PHARMA International Canada Inc. 9400, boul. Langelier Mantreal Canada HIP 3H8.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Sichuan Province Yuxin Pharmaceuticals Co.Ltd No 51,west section of Changjiang road, economic development district (south district) shifang city Sichuan province,China		
API Lot No.	221101		
Description of Pack (Container closure system)	Alu–PVC blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	066NS01	066NS02	066NS03
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	01-04-2023	01-04-2023	01-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Sichuan medical productsAdministration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 06/03/2023 specifying 1.2000Kg.The invoice is cleared by assistant director I & E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1455.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Section approval letter No. 1-18/92-Lic (Vol-III) dated 1301.2022 (Sachet Section-General New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	10.10.2023
	Details of fee submitted	PKR 30,000/- Dated
	The proposed proprietary name / brand name	**DIOCTITE SACHET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Dioctahedral semectite….3g
	Pharmacotherapeutic Group of (API)	Other Intestinal Adsorbents
	Pharmaceutical form of applied drug	Oral sachet
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Smetcta 3g sachet Beaufour Ipsen Industrie France
	For generic drugs (me-too status)	DOCTILE 3g sachet Sami Pharmaceuticals Pvt. Ltd
	Name and address of API manufacturer.	Shandong Xianhe Pharmaceutical Co., Ltd. Xianhe Town, Hekou Country , Dongying City, Shandong Province 257231 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against product, Smecta 3g Sachet
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Xianhe Pharmaceutical Co., Ltd.		
API Lot No.	X220502		
Description of Pack (Container closure system)	Aluminium Sachet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	016NS02	069NS03	069NS04
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	28/12/2022	28/12/2022	28/12/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Food and Drugs Control Administration.The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 31 Aug-2022 specifying 5Kg.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

DEFERRED CASES

1456.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories. B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 002 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 15-08-2022 **Status:** by way of wholesaler **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	M/s Exirnanosina, Unit 7, F1. 4, No. 94, Fathi Shaghagi St., Jahanmehr St., Shahid Gomnam Ave., Fatemi Sq., Tehran, Iran.
	Name, address of manufacturer(s)	M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# 665/113187) issued by Iran Food & Drug Administration dated 21-02-2021. • Free Sale status: The COPP endorses the free sale status of the applied product in Iran. • GMP status: The COPP endorses the GMP status of the manufacturer. • Firm has submitted Legalized GMP certificate (Certificate No. 665/44522) issued by Iran Food & Drug Administration dated 09-02-2022 for M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran	
	Details of letter of authorization / sole agency agreement • Original Legalized Sole Agency Declaration (NOC) issued dated 18-07-2021 by M/s Exirnanosina in name of M/s Gene-Tech Laboratories for SinaDoxosome Injection, has been submitted. • Another agreement between the M/s Zhejiang Hengdian Apeola I&E Co., & M/s Shandong Luoxin Pharmaceutical Group Stock Co; Ltd has also been submitted declaring M/s Zhejiang Hengdian Apeola I&E Co the formal sole distributor of the applied product in Pakistan	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 20055 dated 13-07-2022
	Details of fee submitted	Rs.150,000/- dated 27-06-2022
	The proposed proprietary name / brand name	SinaDoxosome 20mg/ 10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	(Injectable Nanoliposomal Doxorubicin Hydrochloride) Each 10ml Vial Contains: Doxorubicin HCl…….20mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	L01DB01 — Anthracycline topoisomerase inhibitor
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Doxulip 20mg Injection of M/s Revive Pharmakon, Lahore (Reg.087684)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Synbias Pharma ltd., Kreplischikov Street 181, 83085, Donetsk, Ukraine.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months.

Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of Caelyx injection has been submitted.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
Container closure system of the drug product	Type I glass vial
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25°C ±2°C / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5°C ±3°C for 18 months.

The product was considered by the Registration Board in its 330th meeting and deferred for submission of reply for below mentioned shortcomings. The firm has now submitted the response which is tabulated below:

Remarks of Evaluator:

Section#	Observations	Firm's response
	A contract agreement has been submitted b/w Nano Daru Pajuhan Pardis Iran and Genetech Laboratories Karachi. This need to be clarified because another sole agency authorization in your name has also been submitted by the manufacturer i.e. M/s Exirnanosina Company.	Copy of letter by the M/s Exirnanosina, Unit 7, F1. 4, No. 94, Fathi Shaghagi St., Jahanmehr St., Shahid Gomnam Ave., Fatemi Sq., Tehran, Iran wherein they have submitted clarification that they are separate entity which specialize in the production and distribution of Doxorubicin whereas Nano Daru Pajuhan Pardis Iran is separate company and both of them have no connection and affiliation with each other.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL by way of whole sale vide No. 0311 dated 08.02.2023 issued on 31.01.2023 and is valid till 30.01.2028. New License has been issued to the firm.
1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board shall be submitted.	Firm has submitted reference of product of Janssen Inc., Canada (Caelyx (Pegylated Liposomal Doxorubicin Hydrochloride Injection) sterile aqueous suspension for intravenous infusion).
2.3	Information submitted in Table for literary references for drug product is not correct. Revised information shall be submitted along with reference from pharmacopoeia.	The firm has submitted the references of specifcations for the API and excipients.

	3.2.S.2.1	Details of drug substance manufacturer declared in section 1.6.5 are different from that declared in section 3.2.S.2.1.	The firm now submitted they are getting API from M/s Synbias Pharma AG Switzerland which is manufactured by M/s Gemini PharmChem Mannheim GmbH Germany. As evidence copy of GMP certificate issued by the German Authorities is submitted.
	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Exirnanosina shall be submitted.	The firm has submitted the required information
	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the M/s Exirnanosina) shall be submitted.	The firm has submitted the required information
	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by M/s Exirnanosina used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture.	The firm has submitted the required information.
	3.2.P.1	Qualitative composition of applied formulation is different from that of the innovator drug product. Clarification shall be submitted in this regard.	The firm clarified that applied qualitative formulation is same as the Innovator product.
	3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	The pH range is 6.0-6.8 as per specifcations and CoA certificate of analysis submitted by the firm which is same as reference product.
	3.2.P.2.5	Submit compatibility studies with the proposed diluent for dilution.	The firm submitted compatibility studies with dextrose 5% solution for injection which indicates that product is stable for 24 hrs after reconstitution when stored in refrigerator at 2-8 ^{o}C
	3.2.P.5.1	• Justification need to be submitted for referring the USP monograph because the applied liposomal formulation is not available in the same. • Justification shall be submitted for the limit of pH test with reference to Innovator product • Justification shall be submitted for not including test of related substance in drug product specifications with reference to pharmacopoeial monograph. • Justification shall be submitted for variation of limit of Endotoxin test with reference to Innovator product	The firm submitted the in house specifcations with pH limits, impurities and endotoxin limits in line with the reference product.

	.	
3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.	The firm has stability data sheets of three batches rather the batch analysis details.
3.2.P.8.3	• Justification shall be submitted for the limit & results of pH test reported in the stability studies. • Justification shall be submitted for not performing test of related substances in stability studies. • Significant change in the results of Assay test has been reported in the accelerated stability studies of batch no. SD00209601. Justification shall be submitted in this regard. • Out of specification results for of Assay test has been reported in the accelerated stability studies of batch no. SD00209602. Justification shall be submitted in this regard. • Long term stability studies of 18months has been submitted only whereas long term stability study shall be submitted till claimed shelf life.	❖ As liposomal doxorubicin hydrochloride is not in any pharmacopeia, the applied pH I in the limit of the innovator drugs product (Caelyx) and the method of analysis is form pharmacopeia general chapter. ❖ Since the updated reference method of the product is BP, the impurity test has been added to new specification. ❖ According to stability studies the product I stable for 3 months under accelerate conditions (25±3°C, %±5 R.H) due to reduction of assay in month 6. ❖ According to stability studies the product I stable for 3 months under accelerate condition (25±3°C, %±5 R.H) due to reduction of assay in month 6. ❖ The product shelf life is the same as innovator drug (Caelyx) which is 18 months.

Remarks:
As per innovator the identified CQAs of the finished product were appearance, identification of doxorubicin, identification of lipids, pH, osmolality, particulate matter, particle size distribution, zeta potential, assay, related substances, lipid content, lipid degradants, encapsulation efficiency, free drug, drug to lipid ratio, sulfate and ammonium ion concentration, colour, sterility and bacterial endotoxin.

Decision in 331st meeting:
Deferred for submission of following data:
Identification of lipids, osmolality, particle size distribution, zeta potential, lipid content, lipid degradants, encapsulation efficiency, free drug, drug to lipid ratio and sulfate and ammonium ion concentration.

Remarks of Evaluator:
The firm has now submitted revised specifications for the tests mentioned above required by the Board however Drug Product part of dossier is required to confirm the manufacturing and testing of the product as per submitted specifications.

Decision: Deferred for submission of product specifications data as per CTD section 3.2.P.5 (Proposed Specifications, Analytical Procedures, Analytical Method Validation Studies, Batch Analysis Data, Justification of Specifications).

Deputy Director (PEC) (Mr. Salateen Waseem Philip)

Item No. 01: Routine Cases.

1457.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad**
	Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt) Ltd.**

		(DML # 000616) 19-Km Sheikhupura Road Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 30790 Dated: 31-10-2022
	Details of fee submitted	PKR 75,000/-: 05-10-2022 (Slip # 9701593917)
	The proposed proprietary name / brand name	Ticovate plus Nasal Spray
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each spray (0.14g) contains: Azelastine HCl …… 137 mcg Fluticasone Propionate…… 50 mcg
	Pharmacotherapeutic Group of (API)	(histamine H - receptor antagonist and synthetic corticosteroid).
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Health Canada approved Dymista®
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.5.2	Please submit label claim mentioning the quantity of salt as well as base per container, per dose and per actuation.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer (Azeastine) issued by regulatory authority of that country and should be valid till date.	Submitted
3.2.S.7	Please submit stability data of API Azelastine HCl as per climatic condition of Pakistan (Zone IV -A)	Submitted
3.2.P.5	Please provide reference of specification and submit batch analysis report along with reference of Pharmacopeia / innovator spec.	Submitted
3.2.P.8	- Please submit the relevant data of stability batches (chromatograms, calculation sheets, raw data etc) - Please submit DRAP clearance documents for procurement of APIs.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1458.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39370 Dated: 29-12-2022

	Details of fee submitted	PKR 75,000/-: 30-11-2022 (Slip # 4650469971)
	The proposed proprietary name / brand name	ESPRA-X 500/20
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Naproxen (enteric coated core) …… 500 mg Esomeprazole as magnesium tri-hydrate (immediate release coat)…… 20 mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory And Antirheumatic Products, Non Steroids - Priopionic Acid Derivatives
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved VIMOVO
	For generic drugs (me-too status)	Eznepo MR Tablet 500/20mg Reg# 117966 By Wnsfeild Pharmaceuticals
Evaluation by DD-PE&R:		
Decision: approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1459.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals (Pvt) Ltd. (DML # 000052)** **62 Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39369 Dated: 29-12-2022
	Details of fee submitted	PKR 75,000/-: 30-11-2022 (Slip # 459834274873)
	The proposed proprietary name / brand name	Tablet NEXLE-EZ 180/10
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Bempedoic acid …… 180 mg Ezetimibe…… 10 mg
	Pharmacotherapeutic Group of (API)	Cholesterol absorption inhibitor. Lipid modifying agent / ACL Inhibitor
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	Bottle of 30 tablets with child resistant cap.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXLIZET® USFDA approved formulation
	For generic drugs (me-too status)	N/A
Evaluation by DD-PE&R:		

Section	Observations

1.3.4	Please submit notarized copy of contract between contract giver and contract acceptor on stamp paper presenting the capacities of the contract acceptor for the manufacturing sections for whom the products have been applied. Affidavit on stamp paper (showing name, designation, CNIC number of contract giver) stating installed capacity of the contract acceptor for contract manufacturing. This affidavit should be signed by CEO/MD of contract acceptor.
	As CCL is a licensed pharmaceutical manufacturing unit, please provide reasons that why your manufacturing unit is unable to maintain its production or output level with reasons, including but not limited to repair or upgradation requirements?
	Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of M/s Horizon Pharmaceuticals.
3.2.S.7	Please submit the details regarding determination of polymorphic form of API by drug substance manufacturer. Please submit proof that drug substance manufacturer has a well-established and validated XRD method and testing facility for XRD.
3.2.P.2	Please provide invoice for procurement of reference product, batch #, manufacturer details. Is remaining quantity of reference product and the stability batches of your drug product still present in stability chamber?
3.2.P.8	Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.** Please submit complete stability data of 6th months both for accelerated and real time climatic conditions. Please submit reference of choosing dissolution limits of both APIs in drug product.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1460.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safe Pharmaceuticals (Pvt.) Ltd. (DML # 000349)** **Plot # C-120, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Safe Pharmaceuticals (Pvt.) Ltd. (DML # 000349)** **Plot # C-120, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31345: 02-10-2022
	Details of fee submitted	PKR 30,000/-: 26-08-2022 (Slip # 27884048499)
	The proposed proprietary name / brand name	**LIGNOCAINE HCL 1% 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Lignocaine (as HCl) … 10 mg
	Pharmacotherapeutic Group of (API)	Local anesthetic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Lidocaine 1% injection by Healthtek Pharma

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Liquid Injection Ampoule (General) Section.
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.
3.2.P.2	Please submit the comparison of the results of the testing parameters of your drug product vs comparator product for confirmation of Pharmaceutical equivalence.
3.2.P.5	It has been observed that BP specification has been claimed at Section 1.5.6 of Module I while analytical method and specification reflect USP pharmacopeia. It is therefore requested to submit stability data and testing parameters as per BP specification **OR** correct the mistake in section 1.5.6 of Module I along with submission of prescribed fee of PKR 7500/- for correction.
3.2.P.8	Please submit complete six-month stability data of three batches for both accelerated and real time climatic conditions along with stability sheets / calculation sheets and raw data. Please submit COA of API used in manufacturing of the stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1461.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Name, address of Manufacturing site.	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34818: 01-12-2022
	Details of fee submitted	PKR 30,000/-: 28-10-2022 (Slip # 287122464)
	The proposed proprietary name / brand name	**Cefacit Dry Suspension 125mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of reconstituted suspension Contains: Cefaclor monohydrate equivalent to Cefaclor …… 125 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Cevalor 125 mg / 5 ml by Barrett Hodgson

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Oral powder for suspension (Cephalosporin) Section. Please submit section approval letter for grant of Oral Powder for suspension (Cephalosporin) in Central Licensing Board, issued by Licensing Division DRAP.
3.2.P.1	Please submit the comparison of master formulation of your drug product vs innovator product in tabulated form.
3.2.P.5	Please submit system suitability test in the analytical method validation for HPLC as explained in monograph of USP Pharmacopeia.
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches. Please provide information of batch sizes of three stability batches. Please submit calculation sheets of assay which must contain calculation formula as provided in monograph of USP pharmacopeia.

	Please submit chromatograms of assay for complete six month stability data along with calculation sheets.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1462.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Name, address of Manufacturing site.	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34819: 01-12-2022
	Details of fee submitted	PKR 30,000/-: 28-10-2022 (Slip # 21976536545)
	The proposed proprietary name / brand name	**Cefacit Dry Suspension 250mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of reconstituted suspension Contains: Cefaclor monohydrate equivalent to Cefaclor …… 250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Cevalor 250 mg / 5 ml by Barrett Hodgson

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Oral powder for suspension (Cephalosporin) Section. Please submit section approval letter for grant of Oral Powder for suspension (Cephalosporin) in Central Licensing Board, issued by Licensing Division DRAP.
3.2.P.1	Please submit the comparison of master formulation of your drug product vs innovator product in tabulated form.
3.2.P.5	Please submit system suitability test in the analytical method validation for HPLC as explained in monograph of USP Pharmacopeia.
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches. Please provide information of batch sizes of three stability batches. Please submit calculation sheets of assay which must contain calculation formula as provided in monograph of USP pharmacopeia. Please submit chromatograms of assay for complete six month stability data along with calculation sheets.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1463.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Name, address of Manufacturing site.	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33630: 22-11-2022
	Details of fee submitted	PKR 30,000/-: 17-10-2022 (Slip # 1714354721)
	The proposed proprietary name / brand name	**Askprol-JP Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	antipyretic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1000's jar packing
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Paracetamol tablet 500 mg by Zafa

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Tablet (General) Section. Please submit section approval letter for grant of Tablet (General) Section in Central Licensing Board, issued by Licensing Division DRAP.
3.2.P.1	Please submit the comparison of master formulation of your drug product vs innovator product in tabulated form. Please clarify whether your formulation film coated as mentioned in Section 1.5.2 of Module – I or otherwise?
3.2.P.5	Please clarify the specification either USP/BP/JP or others and submit prescribed fee of PKR 7500/- for correction
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1464.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sigma Pharma International (Pvt) Ltd. (DML # 000804)** **Plot No. E-50 North Western Industrial Zone Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	**M/s Sigma Pharma International (Pvt) Ltd.** **Plot No. E-50 North Western Industrial Zone Port Qasim Authority, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34696: 30-11-2022
	Details of fee submitted	PKR 30,000/-: 25-11-2022 (Slip # 5583362410)
	The proposed proprietary name / brand name	**Paracetamol Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	BP Specification

	Proposed Pack size	20 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA & USFDA approved formulation
	For generic drugs (me-too status)	Tablet Panadol by GSK

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1465.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. (DML # 000789) Plot No. 129 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Wimits Pharmaceuticals (Pvt) Ltd. (DML # 000789) Plot No. 129 Sundar Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32898: 16-11-2022
	Details of fee submitted	PKR 30,000/-: 08-11-2022 (Slip # 86138419)
	The proposed proprietary name / brand name	**Peradol Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1 x10s, 2 x 10s, 3 x 10s, 10 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA & USFDA approved formulation
	For generic drugs (me-too status)	Tablet Panadol by GSK

Evaluation by DD-PE&R:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1466.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. (DML # 000789) Plot No. 129 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Wimits Pharmaceuticals (Pvt) Ltd. (DML # 000789) Plot No. 129 Sundar Industrial Estate Lahore.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32897: 16-11-2022
	Details of fee submitted	PKR 30,000/-: 08-11-2022 (Slip # 281066056719)
	The proposed proprietary name / brand name	**Peradol Suspension 160 mg / 5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml Contains: Paracetamol …… 160 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	120 ml amber glass bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA & USFDA approved formulation
	For generic drugs (me-too status)	Panadol Suspension by GSK
Evaluation by DD-PE&R:		
Decision: approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1467.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. (DML # 000644)** **Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Weather Folds Pharmaceuticals. (DML # 000644)** **Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33864: 24-11-2022
	Details of fee submitted	PKR 30,000/-: 30-09-2022 (Slip # 30795566415)
	The proposed proprietary name / brand name	**Macedol Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Tablet Panadol by GSK

Evaluation by DD-PE&R:

Section	**Observations**	**Reply of the firm**

1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.2	Please clarify that how Pharmaceutical equivalence has been performed against Temprin tablet which haven't active ingredient as proposed in your formulation ?	Typo-error, firm has now re-submitted PE results.
3.2.P.8	Please submit COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1468.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals. (DML # 000790) Plot No. 31 & 32 Punjab Small Industrial Estate, Taxila Rawalpindi.**
	Name, address of Manufacturing site.	**M/s Wenovo Pharmaceuticals. (DML # 000790) Plot No. 31 & 32 Punjab Small Industrial Estate, Taxila Rawalpindi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1364: 16-01-2023
	Details of fee submitted	PKR 30,000/-: 29-12-2022 (Slip # 467789996486)
	The proposed proprietary name / brand name	**Pinoma Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Tablet Panadol by GSK

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1469.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt) Ltd. (DML # 000648) 30-Km Multan Road Lahore.**
	Name, address of Manufacturing site.	**M/s Aptcure (Pvt) Ltd. (DML # 000648) 30-Km Multan Road Lahore.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39364: 29-12-2022
	Details of fee submitted	PKR 30,000/-: 15-12-2022 (Slip # 305073124)
	The proposed proprietary name / brand name	**APTOL Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	100s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA & USFDA approved formulation
	For generic drugs (me-too status)	Tablet Panadol by GSK

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit GMP certificate of your firm issued by DRAP which should be valid till date.	Submitted
3.2.P.2	Please submit similarity factor calculation and record of comparative dissolution profile.	Submitted
3.2.P.3	Please clarify the method of manufacturing of tablets either by wet granulation or direct compression?	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1470.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals (Pvt) Ltd. (DML # 000072)** **F-95 Off Hub River Road, SITE Karachi.**
	Name, address of Manufacturing site.	**M/s Sami Pharmaceuticals (Pvt) Ltd. (DML # 000072)** **F-95 Off Hub River Road, SITE Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3929: 16-02-2023
	Details of fee submitted	PKR 30,000/-: 27-01-2023 (Slip # 34756634690)
	The proposed proprietary name / brand name	**Tablet Provas® EXTEND MR 665mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Bilayer Tablet (modified release & immediate release) Contains: Paracetamol …… 665 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	USP Specification

	Proposed Pack size	20s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Tablet Panadol osteo by GSK

Evaluation by DD-PE&R:

Section	Observations
1.5.2	Please clarify in your label claim whether formulation is bilayer tablet or otherwise? Along with total amount API as 665 mg, Please also mention in your label claim the quantity of API in immediate and sustained release layers.
3.2.P.1	Please submit a comparison for the formulation of your drug product with reference product in tabulated form. Please justify that why carnuba wax being not used in your formulation while the reference product formulation uses it in coating.
3.2.P.2	Please clarify that how monograph of extended release tablet of acetaminophen in USP Pharmacopeia is applicable on dissolution and assay tests of bilayer tablet containing both immediate release and sustained release tablets of paracetamol ?
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches issued by both drug substance manufacturer and drug product manufacturer. Please submit procurement documents of API.

Decision: approved. Keeping in view the approval status of product in different reference regulatory authorities, WHO maturity level-4 (ml-4) authorities and pics member countries, registration board approved the instant application along with following conditions as approved previously by registration board in its 331st meeting for applied formulation:

A) manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

B) manufacturer will perform process validation of first three batches of the product as per the commitment submitted in the registration application.

C) complete finished product specifications (in tabulated form) will be annexed with the registration letter.

D) to mitigate the risk due to toxicity associated with overdose of paracetamol extend tablet 665mg, registration letter will be issued with following additional conditions/ statements:

"Following conditions should appear on label of the product in bold and conspicuous manner:

☐ for adults, the highest recommended dose of paracetamol extend tablet 665mg is 1.3 g and the Maximum daily dose is 4 g (i.e., 2 tablets 3 times a day with highest dose of 6 tablets a day).

Paracetamol extend tablet 665mg should not be used as an alternative to panadol/ paracetamol tablet 500mg without prior consultation with physician/ pharmacist."

E) above-mentioned conditions will also be included in advertisement of the product and for this purpose, recommendation will be forwarded to pharmacy services division, drap.

F) to ensure compliance with the above-mentioned conditions, the applicant will be advised to conduct training programmes for the health care providers and submit biannual compliance reports to pe&r division subsequent to issuance of registration.

1471.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories (Pvt) Ltd. (DML # 000232)** **124/1 Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Wilshire Laboratories (Pvt) Ltd. (DML # 000232)** **124/1 Industrial Estate Kot Lakhpat Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 362: 04-01-2023

	Details of fee submitted	PKR 30,000/-: 28-11-2022 (Slip # 71322283237)
	The proposed proprietary name / brand name	**Tablet Paracetamol EXTEND 665mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Bilayer Tablet (modified release & immediate) Contains: Paracetamol …… 665 mg
	Pharmacotherapeutic Group of (API)	Antipyretic / analgesic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	20s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Tablet Panadol osteo by GSK

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit section approval letter for Tablet (General) Section approved by Central Licensing Board in its meeting and letter issued by Licensing Division DRAP.
1.5.2	Please clarify in your label claim whether formulation is bilayer tablet or otherwise?
3.2.P.1	Please submit a comparison for the formulation of your drug product with reference product in tabulated form. Please justify that why carnuba wax being not used in your formulation while the reference product formulation uses it in coating.
3.2.P.2	Please clarify that how monograph of extended release tablet of acetaminophen in USP Pharmacopeia is applicable on dissolution and assay tests of bilayer tablet containing both immediate release and sustained release tablets of paracetamol ?

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1472.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfield Pharmaceuticals. (DML # 000610) Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Wnsfield Pharmaceuticals. (DML # 000610) Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3225: 03-02-2023
	Details of fee submitted	PKR 30,000/-: 11-01-2023 (Slip # 874344950796)
	The proposed proprietary name / brand name	**Tablet Etiroxx 60 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Etoricoxib …… 60 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Tablet Etoxib 60 mg by Hiranis

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter of Oral Tablet dosage form manufacturing facility, issued by Licensing Division DRAP.	Submitted
	Please submit latest / valid GMP certificate of your firm issued by DRAP.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.	Submitted
3.2.P.7	Please submit details of primary container i.e. ALU-ALU, PVC/ALU, Bottle or others.	ALU-ALU Blister
3.2.P.8	Please submit COA of the API used in manufacturing of stability batches. Firm need to submit COA issued by Drug substance manufacturer as well as drug product manufacturer.	Submitted
	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1473.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfield Pharmaceuticals. (DML # 000610) Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Wnsfield Pharmaceuticals. (DML # 000610) Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3226: 03-02-2023
	Details of fee submitted	PKR 30,000/-: 11-01-2023 (Slip # 2947249905)
	The proposed proprietary name / brand name	**Tablet Etiroxx 90 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Etoricoxib …… 90 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Tablet Etoxib 90 mg by Hiranis

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter of Oral Tablet dosage form manufacturing facility, issued by Licensing Division DRAP.	Submitted
	Please submit latest / valid GMP certificate of your firm issued by DRAP.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.	Submitted
3.2.P.7	Please submit details of primary container i.e. ALU-ALU, PVC/ALU, Bottle or others.	ALU-ALU Blister
3.2.P.8	Please submit COA of the API used in manufacturing of stability batches. Firm need to submit COA issued by Drug substance manufacturer as well as drug product manufacturer.	Submitted
	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1474.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt) Ltd. (DML # 000106) Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Tabros Pharma (Pvt) Ltd. (DML # 000106) Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4213: 14-02-2023
	Details of fee submitted	PKR 30,000/-: 14-02-2023 (Slip # 3221619684)
	The proposed proprietary name / brand name	**Savisca Shampoo 2% w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram Contains: Ketoconazole …… 20 mg
	Pharmacotherapeutic Group of (API)	Imidazole Anti-fungal agent
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	60ml, 90ml, 100 ml & 120 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Conaz Scalp lotion (Shampoo based)

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.5.8	Please clarify that formulation applied is in w/w % i.e. 20 mg/gm while the me too generic reference provided is in w/v % i.e. 20 mg / ml.	Our product is formulated with the same weight per weight (w/w) approach as the innovator brand Nizoral Shampoo with a claimed concentration of 20 mg per gram. However, the generic alternative is labeled using weight per volume (w/v) percentage, starting 20 mg per ml, which deviates from the innovator specification.

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1475.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34710: 30-11-2022
	Details of fee submitted	PKR 30,000/-: 25-10-2022 (Slip # 6044129606)
	The proposed proprietary name / brand name	**Tablet Peridol 5 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Haloperidol …… 5 mg
	Pharmacotherapeutic Group of (API)	Anti-epileptic agent
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5 x 10s (ALU/PVC Blister)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Dosik 5 mg Tablet by Adamjee Pharmaceutical

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit GMP certificate of your firm issued by DRAP which should be valid till date.	Submitted
3.2.P.2	Please submit calculation of similarity factor for comparative dissolution profile.	Submitted
3.2.P.8	Please submit report of dissolution and uniformity of dosage form as per monograph of USP pharmacopeia. Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1476.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)**

		112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4043: 13-02-2023
	Details of fee submitted	PKR 30,000/-: 25-10-2022 (Slip # 03468975016)
	The proposed proprietary name / brand name	**Tablet Peridol 10 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Haloperidol …… 10 mg
	Pharmacotherapeutic Group of (API)	Anti-epileptic agent
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5 x 10s (ALU/PVC Blister)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Dosik 10 mg Tablet by Adamjee Pharmaceutical
Evaluation by DD-PE&R:		
Decision: approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1477.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29618: 18-10-2022
	Details of fee submitted	PKR 30,000/-: 27-06-2022 (Slip # 7009998948)
	The proposed proprietary name / brand name	**Tablet Joxetine 10 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each fim coated tablet Contains: Paroxetine HC hemihydrate equivalent to Paroxetine …… 10 mg
	Pharmacotherapeutic Group of (API)	Anti-Psycotic & enti-depressant
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10s (ALU/PVC Blister)
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Health Canada approved formulation
	For generic drugs (me-too status)	Paraxyl by CCL

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit GMP certificate of your firm issued by DRAP which should be valid till date.	Submitted
3.2.P.2	Please submit calculation of similarity factor for comparative dissolution profile.	Submitted
3.2.P.8	Please submit report of dissolution and uniformity of dosage form along with chromatograms, raw data and calculation sheets as per monograph of USP pharmacopeia.	Submitted
	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1478.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	**M/s Jawa Pharmaceuticals (Pvt) Ltd. (DML # 000150)** **112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29619: 18-10-2022
	Details of fee submitted	PKR 30,000/-: 27-06-2022 (Slip # 419560752)
	The proposed proprietary name / brand name	**Tablet Joxetine 20 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each fim coated tablet Contains: Paroxetine HC hemihydrate equivalent to Paroxetine …… 20 mg
	Pharmacotherapeutic Group of (API)	Anti-Psycotic & enti-depressant
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10s (ALU/PVC Blister)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Health Canada approved formulation
	For generic drugs (me-too status)	Paraxyl by CCL

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit GMP certificate of your firm issued by DRAP which should be valid till date.	Submitted
3.2.P.2	Please submit calculation of similarity factor for comparative dissolution profile.	Submitted
3.2.P.8	Please submit report of dissolution and uniformity of dosage form along with chromatograms, raw data and calculation sheets as per monograph of USP pharmacopeia.	Submitted
	Please submit DRAP clearance documents for procurement of API.	Submitted

	Please clarify that why manual peak integration has been utilized in assay of drug product while peak integration is allowed only in case of impurity testing?	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**.

1479.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmasol (Pvt) Ltd. (DML # 000872) Plot 549, Sunder Industrial estate, Lahore.**
	Name, address of Manufacturing site.	**M/s Pharmasol (Pvt) Ltd. (DML # 000872) Plot 549, Sunder Industrial estate, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31974: 04-11-2022
	Details of fee submitted	PKR 30,000/-: 25-10-2022 (Slip # 596476748)
	The proposed proprietary name / brand name	**Tablet Linaglip 5 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Linagliptin…… 5 mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10s, 14s, 20s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Linvesta 5 mg Tablet by Wilshire

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit GMP certificate of your firm issued by DRAP which should be valid till date.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**.

1480.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt) Ltd. (DML # 000785) Plot No. E-145 to E-149 North Western Industrial Zone Port Qasim, Karachi.**
	Name, address of Manufacturing site.	**M/s Hiranis Pharmaceuticals (Pvt) Ltd. (DML # 000785) Plot No. E-145 to E-149 North Western Industrial Zone Port Qasim, Karachi.**
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36506: 15-12-2022
	Details of fee submitted	PKR 30,000/-: 06-12-2022 (Slip # 94584999472)
	The proposed proprietary name / brand name	**Tablet Ivmac 6 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Ivermectin …… 6 mg
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**STROMECTOL®**- USFDA approved formulation ***(discontinued)*** *****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*****
	For generic drugs (me-too status)	Ivermite 6 mg Tablet by Atco
Evaluation by DD-PE&R:		
Decision: approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1481.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt) Ltd. (DML # 000415)** **A/20 North Western Industries Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	**M/s Platinum Pharmaceuticals (Pvt) Ltd. (DML # 000415)** **A/20 North Western Industries Zone Bin Qasim Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 39627: 30-12-2022
	Details of fee submitted	PKR 75,000/-: 21-12-2022 (Slip # 6331908108)
	The proposed proprietary name / brand name	**Tablet Deafloxacin 450 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Delafloxacin meglumine equivalent 649 mg to Delafloxacin …… 450 mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5's, 10's & 100's.

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Baxdela ® - USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.5.2	Please mention the quantity of salt and base per unit. Also elaborate about type of tablet (uncoated/film coated / sugar coated etc.).	Submitted
1.5.11	As delafloxacin is a member of the fluoroquinolone class of antibacterial drugs, please include safety issues related to the class in relevant sections of labelling including the Boxed warning and Precautions section.	Submitted
3.2.S.7	Please submit the details regarding determination of polymorphic form of API by drug substance manufacturer.	It is mentioned in section 3.2.S.1.3 of DMF that API by the manufacturer doesn't contain crystal water so its anhydrous crystal form compound which is consistent with anhydrous crystal form of U.S Patent.
3.2.P.1	Delafloxacin meglumine is a poorly soluble compound, please provide details for designing the proposed drug product to be a very rapidly disintegrating dosage form.	We have formulated our product as per the Innovator formula of Baxdela tablet. Innovators Formula contains Crospovidone (109mg/tab) as a disintegrant and solubility enhancer.
3.2.P.2	Please clarify your position for pasting results of assay and dissolution test of escitalopram in summary sheet of pharmaceutical equivalence of tablets containing delafloxacin meglumin.	Written Escitalopram in pharmaceutical equivalence summary of delafloxacin 450mg tablet is a typographic error. Corrected document of pharmaceutical equivalence summary of Delafloxacin 450mg tablet is attached
	Please provide invoice for procurement of Tablet Baxdela, batch #, manufacturer details.	Submitted
	Is remaining quantity of Tablet Baxdela and the stability batches of your drug product still present in stability chamber?	Stability batches remaining quantity still available while reference product sample not present.
	Please justify that how stability of comparator product equivalent to your drug product while the primary container of products is different.	Comparator product packed in HDPE bottles and applicant's ALU-ALU blister equivalent to each other. Manufcaturing of comparator product was 04-2021 while our product manufacture on 04-2022 but even after 12 months, applicant results are equivalent to reference product.
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1482.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd. (DML # 000577)**

		21-Km Ferozepur Road Near Masjid Ibrahim Lahore.
	Name, address of Manufacturing site.	**M/s Shrooq Pharmaceuticals (Pvt) Ltd. (DML # 000577)** **21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3221: 03-02-2023
	Details of fee submitted	PKR 75,000/-: 13-07-2022 (Slip # 93527178610)
	The proposed proprietary name / brand name	**Tablet Etromo 25 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Etrombopag olamine equivalent to Etrombopag……25 mg
	Pharmacotherapeutic Group of (API)	Thrombopoietin Receptor Antagonist
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	28 tablets per pack.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Promacta ® USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations
1.1	Please submit remaining fee of PKR 45000/- for registration of New Drugs Application.
1.3.4	Please submit section approval letter issued by Licensing Division DRAP for manufacturing facility of Tablet (general) Section required for this dosage form.
1.5.2	Please mention the quantity of salt and base per unit. Also elaborate about type of tablet (uncoated/film coated / sugar coated etc.).
3.2.S.4	Please submit in detail for the procedures adopted by drug substance manufacturer to determine the polymorphic forms.
3.2.P.2	Please submit invoice for procurement of comparator product. Also submit details regarding Batch #, quantity purchased, mfg. and expiry date. Also submit details of quantity remaining of comparator product.
3.2.P.5	How will you justify the assay method on UV spectroscopy while innovator brands testing method is on HPLC? Please submit reference and validation data to proof that UV spectroscopy method is authentic and reliable than HPLC.
3.2.P.8	Please submit DRAP clearance documents for procurement of API. Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1483.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590)** **28-Km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590)** **28-Km Ferozepur Road Lahore**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5101: 22-02-2023
	Details of fee submitted	PKR 30,000/-: 08-02-2023 (Slip # 379932060)
	The proposed proprietary name / brand name	**Water for injection 2 ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Sterilized Water for injection……2 ml
	Pharmacotherapeutic Group of (API)	Solvent and diluting agent
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	USP type I clear glass ampoule 2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Locally registered
Evaluation by DD-PE&R:		
Decision: approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**.		
1484.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt) Ltd.** **(DML # 000590)** **28-Km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	**M/s NovaMed Pharmaceuticals (Pvt) Ltd.** **(DML # 000590)** **28-Km Ferozepur Road Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36125: 12-12-2022
	Details of fee submitted	PKR 75,000/-: 06-12-2022 (Slip # 45432679)
	The proposed proprietary name / brand name	**Rebamide Tablet 100 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rebamipide …… 100 mg
	Pharmacotherapeutic Group of (API)	Gastro protective agent (Stimulates prostaglandin generation in gastric mucosa)
	Reference to Finished product specifications	JP Specification
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mucosta® PMDA Japan approved formulation
	For generic drugs (me-too status)	Mucosta ® by Otsuka Pakistan.

Evaluation by DD-PE&R:

Section	Observations	Status

3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1485.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590) 28-Km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590) 28-Km Ferozepur Road Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36126: 12-12-2022
	Details of fee submitted	PKR 75,000/-: 02-12-2022 (Slip # 8775736737)
	The proposed proprietary name / brand name	**Baricit Tablet 2 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 2 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK) ATC Code: L04AF02
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.3	The innovator product used roller compaction method for making granules by dry granulation. Please provide complete details of method used to make granules in your formulation.	Product is manufactured by using dry mixing technique as all ingredients used in the formulation are by direct compression grade, so there is no need of compaction, as materials are directly compressible.
	As mentioned in the equipment (Cone blender) for manufacturing process, please clarify the particle size of active and inactive ingredients before passing through mesh # 30.	Since no granulation technique was used so materials were passed through sieve # 30 to remove lumps in the ingredients.
	Please explain the method to confirm the tensile strength as per tablet dimension.	Submitted
	Please provide the percentage of active and inactive ingredients per tablet.	Submitted
	Please mention the volume of coating solution, rate and temperature control by automated system?	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1486.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590) 28-Km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	**M/s NovaMed Pharmaceuticals (Pvt) Ltd. (DML # 000590) 28-Km Ferozepur Road Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36127: 12-12-2022
	Details of fee submitted	PKR 75,000/-: 02-12-2022 (Slip # 327424341042)
	The proposed proprietary name / brand name	**Baricit Tablet 4 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 4 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK) ATC Code: L04AF02
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.3	The innovator product used roller compaction method for making granules by dry granulation. Please provide complete details of method used to make granules in your formulation.	Product is manufactured by using dry mixing technique as all ingredients used in the formulation are by direct compression grade, so there is no need of compaction, as materials are directly compressible.
	As mentioned in the equipment (Cone blender) for manufacturing process, please clarify the particle size of active and inactive ingredients before passing through mesh # 30.	Since no granulation technique was used so materials were passed through sieve # 30 to remove lumps in the ingrdients.
	Please explain the method to confirm the tensile strength as per tablet dimension.	Submitted
	Please provide the percentage of active and inactive ingredients per tablet.	Submitted
	Please mention the volume of coating solution, rate and temperature control by automated system?	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1487.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5491: 27-02-2023
	Details of fee submitted	PKR 30,000/-: 10-02-2023 (Slip # 8379404741)
	The proposed proprietary name / brand name	**TABLET TAPENT 75 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol …… 75 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA® PMDA Japan approved formulation
	For generic drugs (me-too status)	Tablet Tapento 75 mg by Sami Pharmaceuticals.

Evaluation by DD-PE&R:

Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Section	Observations	Reply of the firm
1.3.4	Please submit GMP certificate of the firm issued by DRAP which should be valid till date.	Expired, applied for the fresh.
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.	Submitted
3.2.S.4	Please submit documented evidence that drug substance manufacturer has established method and facility to determine enantiomeric purity.	Submitted
3.2.P.1	Please clarify that why methanol has been used as a solvent in coating of tablets while it is not part of the formulation of innovator brand?	The methanol is used as solvent in the coating solution. However, the methanol is evaporated while coating. The finished product doesn't contain methanol contents.
	Please clarify that why excipients of your formulation are different than the formulation of the innovator brand ?	The quaititative composition of the product is amost similar to that of innovator product, however few excipients used in the coatin of product are different. Stability

		studies depicts that these excipients are compatible with the API.
3.2.P.8	Please clarify that why analytical method has not been validated properly to remove the negative peaks (drifts) in the chromatograms of sample of drug products? The baseline is also not stable in your chromatograms ?	The method defined by the raw material manufacturer was adopted for the testing of product. As the API manufacturer has validated the method. So the Aulton Pharma being the finished product manufacturer has not validated instead verified the analytical procedure.

Comments of Evaluater: The firm is using methanol in coating of tablets while the formulations approved by RRA does not contains organic solvents or methanol as coating solvent. Product is also not light sensitive or moisture sensitive to be coated with any organic solvent.
Firm needs to provide evidence of testing facility of gas chromatography to test the product to be free from traces of methanol along with process validation.
GMP certificate of firm also expired.

Decision: Deferred for the submission of clarification of using methanol in coating of tablets against the practices of RRA and GMP certificate along with report showing the tsting facilities of the firm.

1488.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt) Ltd. (DML # 000785) Plot No. E-145 to E-149 North Western Industrial Zone Port Qasim, Karachi.**
	Name, address of Manufacturing site.	**M/s Hiranis Pharmaceuticals (Pvt) Ltd. (DML # 000785) Plot No. E-145 to E-149 North Western Industrial Zone Port Qasim, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2735: 31-01-2023
	Details of fee submitted	PKR 75,000/-: 18-01-2023 (Slip # 82629045598)
	The proposed proprietary name / brand name	**TABLET TAPENT 75 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol …… 75 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA® USFDA approved formulation
	For generic drugs (me-too status)	Tablet Tapento 75 mg by Sami Pharmaceuticals.

Evaluation by DD-PE&R:
Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1489.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals (DML # 000667)** **3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad.**
	Name, address of Manufacturing site.	**M/s Axis Pharmaceuticals (DML # 000667)** **3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 839: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 22-12-2022 (Slip # 835612326247)
	The proposed proprietary name / brand name	**TABLET TAPONIX 75 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain-ns: Tapentadol …… 75 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA® PMDA Japan approved formulation
	For generic drugs (me-too status)	Tablet Tapento 75 mg by Sami Pharmaceuticals.

Evaluation by DD-PE&R:

Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Section	Observations
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.
3.2.S.4	Please submit documented evidence that drug substance manufacturer has established method and facility to determine enantiomeric purity.
3.2.P.1	Please submit the details of excipients used in coating of the drug product ? also clarify thay why excipients used in reference product are not fully followed in your formulation ?
3.2.P.8	Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.** https://www.dra.gov.pk/wp-content/uploads/2022/01/Guidance-Document-on-CTD-Doc-No.-PER-GL-AF-004.pdf.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1490.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals. (DML # 000778)** **Plot No. 1 & 2 Street No. S-2 RCCI Industrial Estate Rawat.**

	Name, address of Manufacturing site.	**M/s Crystolite Pharmaceuticals. (DML # 000778)** **Plot No. 1 & 2 Street No. S-2 RCCI Industrial Estate Rawat.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34695: 30-11-2022
	Details of fee submitted	PKR 75,000/-: 02-11-2022 (Slip # 4217107410)
	The proposed proprietary name / brand name	**Tablet Folligro 2.5 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Minoxidil …… 2.5 mg
	Pharmacotherapeutic Group of (API)	Pyrimidine derivatives
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	60 tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.3.4	Please submit GMP certificate of the firm issued by DRAP which should be valid till date.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.	Submitted
3.2.P.3	Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets.	Submitted
	Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation.	Submitted
3.2.P.8	Please mention the batch size of stability batches.	Submitted
	Also mention the R & D equipment used in manufacturing of stability batches.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**.

1491.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd.** **(DML # 000851)** **Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Name, address of Manufacturing site.	**M/s Maxitech Pharma (Pvt) Ltd.** **(DML # 000851)** **Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33814: 23-11-2022
	Details of fee submitted	PKR 75,000/-: 02-11-2022 (Slip # 22879641)
	The proposed proprietary name / brand name	**Tablet Tedilid 200 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tedizolid phosphate …… 200 mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	6's, 12's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation Sivextro® 200 mg Tablet
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations
3.2.P.1	Please justify that why overage of 5% added in the formulation?
3.2.P.3	Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets. Please justify that why dry granulation method has been adopted while innovator brand manufactured by wet granulation? Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation. Please mention the volume of coating solution, rate and temperature control by automated system?
3.2.P.8	Please mention the number of tablets manufactured per 0.40kg of batch size.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1492.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33956: 24-11-2022
	Details of fee submitted	PKR 75,000/-: 21-11-2022 (Slip # 677160954)
	The proposed proprietary name / brand name	**Tablet Tapenzon XR 100 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Tapentadol as HCl…… 100 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	NUCYNTA ER® USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by US-DEA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. A pharmacology study demonstrated that tapentadol demonstrated abuse potential comparable to that of hydromorphone.

Section	Observations	Status
1.5.8	Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by US-DEA. Such drugs are sought by drug abusers and people with addiction disorders. Please submt label of the product with precautions.	Submitted
3.2.P.1	Please submit the formulation details regarding release mechanism and kinetics.	Submitted
3.2.P.2	Please submit the details regarding manufacturer and the country from which reference product has been procured. Is any quantity of reference product left ?	Submitted
3.2.P.3	Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets.	Submitted
	Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation.	Submitted
	Please mention the volume of coating solution, rate and temperature control by automated system?	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1493.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33957: 24-11-2022
	Details of fee submitted	PKR 75,000/-: 21-11-2022 (Slip # 590176350)
	The proposed proprietary name / brand name	**Tablet Tapenzon XR 150 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Tapentadol as HCl…… 150 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA ER® USFDA approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by US-DEA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. A pharmacology study demonstrated that tapentadol demonstrated abuse potential comparable to that of hydromorphone.

Section	Observations	Status
1.5.8	Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by US-DEA. Such drugs are sought by drug abusers and people with addiction disorders. Please submt label of the product with precautions.	Submitted
3.2.P.1	Please submit the formulation details regarding release mechanism and kinetics.	Submitted
3.2.P.2	Please submit the details regarding manufacturer and the country from which reference product has been procured. Is any quantity of reference product left ?	Submitted
3.2.P.3	Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets.	Submitted
	Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation.	Submitted
	Please mention the volume of coating solution, rate and temperature control by automated system?	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1494.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37585: 23-12-2022
	Details of fee submitted	PKR 75,000/-: 15-12-2022 (Slip # 6117026118)
	The proposed proprietary name / brand name	**Tablet Eldum 90 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib …… 90 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Formulation registered for Hiranis pharma

Evaluation by DD-PE&R:

Section	Observations
3.2.S.4.1	As mentioned on the COA of drug product manufacturer regarding results of related compound of API. Please submit the relevant data (chromatograms, raw data, calculation sheets).

3.2.P.8	Please submit reference of analytical method via UV spectroscopy used for dissolution test of tablets. It has been observed in the chromatograms submitted for stability batches that peak integrations has been altered for each peak. Please clarify.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1495.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36124: 12-12-2022
	Details of fee submitted	PKR 30,000/-: 27-10-2022 (Slip # 232584861)
	The proposed proprietary name / brand name	**Tablet Betriq XR 50 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains: Mirabegron …… 50 mg
	Pharmacotherapeutic Group of (API)	beta-3 agonist
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 20's, 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Registered for Martin Dow Pharma in 322nd DRB meeting.

Evaluation by DD-PE&R:

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1496.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36123: 12-12-2022
	Details of fee submitted	PKR 30,000/-: 27-10-2022 (Slip # 4954636166)

	The proposed proprietary name / brand name	**Tablet Betriq XR 25 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains: Mirabegron …… 25 mg
	Pharmacotherapeutic Group of (API)	beta-3 agonist
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 20's, 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Registered for Martin Dow Pharma in 322nd DRB meeting.
Evaluation by DD-PE&R:		
Decision: approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1497.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceutical (Pvt) Ltd.** **(DML # 000333)** **14-Km Adyala Road Post Office Dahgai Rawalpindi**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceutical (Pvt) Ltd.** **(DML # 000333)** **14-Km Adyala Road Post Office Dahgai Rawalpindi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 602: 06-01-2023
	Details of fee submitted	PKR 30,000/-: 30-12-2022 (Slip # 95499216001)
	The proposed proprietary name / brand name	**Tablet CIOP 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin …… 250 mg
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Ciproxin by Bayer
Evaluation by DD-PE&R:		

Section	Observations
1.3.4	Please submit section approval letter for Tablet (General) Section issued by Licensing Division

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1498.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceutical (Pvt) Ltd. (DML # 000333) 14-Km Adyala Road Post Office Dahgai Rawalpindi**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceutical (Pvt) Ltd. (DML # 000333) 14-Km Adyala Road Post Office Dahgai Rawalpindi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1360 : 06-01-2023
	Details of fee submitted	PKR 30,000/-: 30-12-2022 (Slip # 00320280925)
	The proposed proprietary name / brand name	**Tablet CIOP 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin …… 500 mg
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Ciproxin by Bayer

Evaluation by DD-PE&R:

Section	Observations
1.3.4	Please submit section approval letter for Tablet (General) Section issued by Licensing Division

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1499.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. (DML # 000498) Plot No. 5-D, Sector I-10/3 Islamabad.**
	Name, address of Manufacturing site.	**M/s Scotmann Pharmaceuticals. (DML # 000498) Plot No. 5-D, Sector I-10/3 Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 708 : 09-01-2023
	Details of fee submitted	PKR 30,000/-: 21-07-2022

		(Slip # 891053276)
	The proposed proprietary name / brand name	**KTI injection 30 mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketorolac Tromethamine …… 30 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Toradol Injection

Evaluation by DD-PE&R:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1500.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. (DML # 000239) 387-388 Sector I-9 Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Wilson's Pharmaceuticals. (DML # 000239) 387-388 Sector I-9 Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1854 : 09-01-2023
	Details of fee submitted	PKR 75,000/-: 11-01-2023 (Slip # 90514292378)
	The proposed proprietary name / brand name	**Colynol Night time Severe Cough**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Paracetamol …… 650 mg Diphenhydramine HCl ……25 mg Phenylephrine HC ……... 10 mg
	Pharmacotherapeutic Group of (API)	Cough Suppressants & expectorants
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's Sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Theraflu Sachet – Novartis Germany
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Status
3.2.P.2	Please submit manufacturer name, batch #, quantity procured for reference product.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1501.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488) Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488) Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 482 : 05-01-2023
	Details of fee submitted	PKR 30,000/-: 28-12-2022 (Slip # 29605847)
	The proposed proprietary name / brand name	**Gynozole Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Miconazole nitrate …….. 20 mg
	Pharmacotherapeutic Group of (API)	(Antifungals for dermatological/ topical use; imidazole derivative) ATC code: D01A C02.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	20g tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Locally registered

Evaluation by DD-PE&R:

Section	Observations
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.
3.2.S.4	Please submit system suitability test for miconazole to confirm the resolution limit in USP specification.
3.2.S.5	Please submit batch analysis report of API along with chromatograms and calculation sheets.
3.2.S.7	Please submit clear copies of stability data which should be readable.
3.2.P.1	Please clarify that why formulation is not same as per the reference product? Please submit in tabulated form the comparison between your formulation and reference product. Please also clarify that why methyl paraben and propyl paraben has been used in formulation instead of benzoic acid?
3.2.P.2	Please submit documented evidence for the reference of assay limits of 75% - 133% for miconazole.
3.2.P.5	Please submit system suitability as per latest monograph USP specification and submit chromatograms to confirm the resolution between peaks are within the limits.
3.2.P.8	Please submit the DRAP clearance document for procurement of API. Please submit the details of HPLC used to perform stability studies and explain that why metadata (sample information window) has been set blank in your chromatograms? Please submit the calculation sheets which must contain formula used, weigh of standard samples in mg and the number of dilution for making final concentration in mg/ml.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1502.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488) Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488)**

		Plot No. 241 Sector 24 Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29751 : 20-10-2022
	Details of fee submitted	PKR 30,000/-: 16-09-2022 (Slip # 944856782)
	The proposed proprietary name / brand name	**Nizoral Cream 2%w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Ketoconazole …….... 20 mg
	Pharmacotherapeutic Group of (API)	(Antifungals for dermatological/ topical use; imidazole derivative) ATC code: D01A C02.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	20g tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Locally registered

Evaluation by DD-PE&R:

Section	Observations
Module I	Please properly fill each and every section of Module I which should be readable.
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.
3.2.S.4	Please submit system suitability test for ketoconazole to confirm the resolution limit in BP specification.
3.2.S.5	Please submit batch analysis report of API along with chromatograms and calculation sheets.
3.2.P.1	Please clarify that why formulation is not same as per the reference product? Please submit in tabulated form the comparison between your formulation and reference product. Please also clarify that why parabens has been used in formulation?
3.2.P.5	Please submit system suitability as per latest monograph BP specification and submit chromatograms to confirm the resolution between peaks are within the limits.
3.2.P.8	Please submit the DRAP clearance document for procurement of API. Please submit the calculation sheets which must contain formula used, weigh of standard samples in mg and the number of dilution for making final concentration in mg/ml. Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1503.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488) Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488) Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29752 : 20-10-2022
	Details of fee submitted	PKR 30,000/-: 23-09-2022 (Slip # 6913334188)
	The proposed proprietary name / brand name	**M-ZOL 0.75% Vaginal Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of gel contains: Metronidazole …….. 7.5 mg
	Pharmacotherapeutic Group of (API)	(Antifungals for dermatological/ topical use; imidazole derivative) ATC code: D01A C02.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	15g tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Health Canada approved formulation
	For generic drugs (me-too status)	Locally registered

Evaluation by DD-PE&R:

Section	Observations
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.
3.2.S.5	Please submit batch analysis report of API along with chromatograms and calculation sheets.
3.2.P.1	Please clarify that why formulation is not same as per the reference product? Please submit in tabulated form the comparison between your formulation and reference product. Please also clarify that why parabens has been used in formulation?
3.2.P.5	Please submit system suitability as per latest monograph USP specification and submit chromatograms to confirm the resolution between peaks are within the limits.
3.2.P.8	Please submit the DRAP clearance document for procurement of API. Please submit the calculation sheets which must contain formula used, weigh of standard samples in mg and the number of dilution for making final concentration in mg/ml. Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

1504.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th-16th October 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 37084 dated 20-12-2022
	Details of fee submitted	PKR 30,000/-: Dated 07-12-2022 Slip # 6120704386
	The proposed proprietary name / brand name	Covance-H Tablet 10mg/160mg/12.5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to Amlodipine ……...……10 mg Valsartan ……160 mg Hydrochlorothiazide …… 12.5 mg
	Pharmaco-therapeutic Group of (API)	A combination of calcium channel blocker, ARB & Diuretics
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT, MHRA, USFDA, EMA & TGA approved formulation.
	For generic drugs (me-too status)	Brand Name: Avsar Plus Tablet Manufacturer: M/s PharmEvo Registration #: 076362
	Name and address of API manufacturer.	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. GMP validity: 20-10-2024 **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. GMP validity: 04-10-2024 **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India. GMP validity: 29-05-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amlodipine Beysalate** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Valsartan** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Hydrochlorothiazide** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Tablet ExForge-HCT **Manufacturer:** M/s Novartis, Spain **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India.		
API Lot No.	Amlodipine Besylate	Valsartan	Hydrochlorothiazide

	20ADL003	6781912601	20HZ00068
Description of Pack (Container closure system)	14 film coated tablets packed in ALU-ALU blister, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CHTab-004	CHTab-005	CHTab-006
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	30-12-2020	30-12-2020	30-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine Besylate** **Quantity:** 30kg **Invoice:** 3202040334 **Dated:** 09-06-2020 **VALSARTAN** **Quantity:** 200 kg **Invoice:** RD2020032301-1 **Dated:** 01-04-2020 **Hydrochlorothiazide** **Quantity:** 125 kg **Invoice:** EI/3092100690 **Dated:** 12-02-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1505.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th-16th October 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 37084 dated 20-12-2022
	Details of fee submitted	PKR 30,000/-: Dated 07-12-2022 Slip # 6120704386
	The proposed proprietary name / brand name	Covance-H Tablet 10mg/160mg/25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to Amlodipine ……...……10 mg Valsartan ……160 mg Hydrochlorothiazide …… 25 mg
	Pharmaco-therapeutic Group of (API)	A combination of calcium channel blocker, ARB & Diuretics
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT, MHRA, USFDA, EMA & TGA approved formulation.
	For generic drugs (me-too status)	Brand Name: Avsar Plus Tablet Manufacturer: M/s PharmEvo Registration #: 076359
	Name and address of API manufacturer.	**<u>Amlodipine Beysalate</u>** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. GMP validity: 20-10-2024 **<u>Valsartan</u>** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd.

		Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. GMP validity: 04-10-2024 **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India. GMP validity: 29-05-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amlodipine Beysalate** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Valsartan** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Hydrochlorothiazide** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Tablet ExForge-HCT **Manufacturer:** M/s Novartis, Spain **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India.		
API Lot No.	Amlodipine Besylate	Valsartan	Hydrochlorothiazide
	20ADL003	6781912601	20HZ00068
Description of Pack (Container closure system)	14 film coated tablets packed in ALU-ALU blister, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CHTab-010	CHTab-011	CHTab-012
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	22-12-2020	22-12-2020	22-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine Besylate** **Quantity:** 30kg **Invoice:** 3202040334 **Dated:** 09-06-2020 **VALSARTAN** **Quantity:** 200 kg **Invoice:** RD2020032301-1 **Dated:** 01-04-2020 **Hydrochlorothiazide** **Quantity:** 125 kg **Invoice:** EI/3092100690 **Dated:** 12-02-2020

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1506.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th-16th October 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 37086 dated 20-12-2022
	Details of fee submitted	PKR 30,000/-: Dated 07-12-2022 Slip # 58266670
	The proposed proprietary name / brand name	Covance-H Tablet 10mg/320mg/25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to Amlodipine ……...……10 mg Valsartan ……320 mg Hydrochlorothiazide …… 25 mg
	Pharmaco-therapeutic Group of (API)	A combination of calcium channel blocker, ARB & Diuretics
	Pharmaceutical form of applied drug	Film Coated Tablet

	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT, MHRA, USFDA, EMA & TGA approved formulation.
	For generic drugs (me-too status)	Brand Name: Avsar Plus Tablet Manufacturer: M/s PharmEvo Registration #: 076360
	Name and address of API manufacturer.	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. GMP validity: 20-10-2024 **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. GMP validity: 04-10-2024 **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India. GMP validity: 29-05-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amlodipine Beysalate** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Valsartan** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Hydrochlorothiazide** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months

		Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Tablet ExForge-HCT **Manufacturer:** M/s Novartis, Spain **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>Amlodipine Beysalate</u>** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. **<u>Valsartan</u>** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. **<u>Hydrochlorothiazide</u>** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India.		
API Lot No.	Amlodipine Besylate	Valsartan	Hydrochlorothiazide
	20ADL003	6781912601	20HZ00068
Description of Pack (Container closure system)	14 film coated tablets packed in ALU-ALU blister, packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CHTab-013	CHTab-014	CHTab-015
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	15-12-2020	15-12-2020	15-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine Besylate** **Quantity:** 30kg **Invoice:** 3202040334 **Dated:** 09-06-2020 **VALSARTAN** **Quantity:** 200 kg **Invoice:** RD2020032301-1 **Dated:** 01-04-2020 **Hydrochlorothiazide** **Quantity:** 125 kg **Invoice:** EI/3092100690 **Dated:** 12-02-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1507.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th-16th October 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 37083 dated 20-12-2022

	Details of fee submitted	PKR 30,000/-: Dated 07-12-2022 Slip # 001567623135
	The proposed proprietary name / brand name	Covance-H Tablet 5mg/160mg/25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to Amlodipine ……...……5 mg Valsartan ……160 mg Hydrochlorothiazide …… 25 mg
	Pharmaco-therapeutic Group of (API)	A combination of calcium channel blocker, ARB & Diuretics
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT, MHRA, USFDA, EMA & TGA approved formulation.
	For generic drugs (me-too status)	Brand Name: Avsar Plus Tablet Manufacturer: M/s PharmEvo Registration #: 076358
	Name and address of API manufacturer.	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. GMP validity: 20-10-2024 **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. GMP validity: 04-10-2024 **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India. GMP validity: 29-05-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amlodipine Beysalate** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Valsartan** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **Hydrochlorothiazide** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Tablet ExForge-HCT **Manufacturer:** M/s Novartis, Spain **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India.		
API Lot No.	Amlodipine Besylate	Valsartan	Hydrochlorothiazide
	20ADL003	6781912601	20HZ00068
Description of Pack (Container closure system)	14 film coated tablets packed in ALU-ALU blister, packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CHTab-007	CHTab-008	CHTab-009
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	07-12-2020	07-12-2020	07-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine Besylate** **Quantity:** 30kg **Invoice:** 3202040334 **Dated:** 09-06-2020 **VALSARTAN** **Quantity:** 200 kg **Invoice:** RD2020032301-1 **Dated:** 01-04-2020 **Hydrochlorothiazide** **Quantity:** 125 kg **Invoice:** EI/3092100690 **Dated:** 12-02-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1508.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th-16th October 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 37082 dated 20-12-2022
	Details of fee submitted	PKR 30,000/-: Dated 07-12-2022 Slip # 34468083157
	The proposed proprietary name / brand name	Covance-H Tablet 5mg/160mg/12.5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to Amlodipine ……...……5 mg Valsartan ……160 mg Hydrochlorothiazide …… 12.5 mg
	Pharmaco-therapeutic Group of (API)	A combination of calcium channel blocker, ARB & Diuretics
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT, MHRA, USFDA, EMA & TGA approved formulation.
	For generic drugs (me-too status)	Brand Name: Avsar Plus Tablet Manufacturer: M/s PharmEvo Registration #: 076357
	Name and address of API manufacturer.	**Amlodipine Beysalate** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. GMP validity: 20-10-2024 **Valsartan** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd. Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. GMP validity: 04-10-2024 **Hydrochlorothiazide** Name: M/s CTX Life Sciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India. GMP validity: 29-05-2025

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**<u>Amlodipine Beysalate</u>** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **<u>Valsartan</u>** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH **<u>Hydrochlorothiazide</u>** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Tablet ExForge-HCT **Manufacturer:** M/s Novartis, Spain **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	**<u>Amlodipine Beysalate</u>** Name: M/s Cadila Pharmaceuticals Ltd. Address: 294, G.I.D.C, Estate City, Anlleshwar-393002, Dist-Bharuch, Gujarat Estate, India. **<u>Valsartan</u>** Name: M/s Zhuhai Rundu Pharmaceutical Co. Ltd.	

	Address: No. 06, North Airport Road, Sanzao Town, Jinwan, District, Zhuhai, Guangdong, China. **Hydrochlorothiazide** Name: M/s CTX LifeSciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255,256/P, 258/P, 276/P, 277,278/P,279 to 282,283/P,284/P GIDC, City-Sachin, Dist. Surat Gujarat Estate, India.			
API Lot No.	Amlodipine Besylate	Valsartan	Hydrochlorothiazide	
	20ADL003	6781912601	20HZ00068	
Description of Pack (Container closure system)	14 film coated tablets packed in ALU-ALU blister, packed in unit carton.			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	Real time: 06 months Accelerated: 06 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)			
Batch No.	CHTab-001	CHTab-002	CHTab-003	
Batch Size	1500 tablets	1500 tablets	1500 tablets	
Manufacturing Date	10-2020	10-2020	10-2020	
Date of Initiation	11-11-2020	11-11-2020	11-11-2020	
No. of Batches	03			

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine Besylate** **Quantity:** 30kg **Invoice:** 3202040334 **Dated:** 09-06-2020 **VALSARTAN** **Quantity:** 200 kg **Invoice:** RD2020032301-1 **Dated:** 01-04-2020 **Hydrochlorothiazide** **Quantity:** 125 kg **Invoice:** EI/3092100690 **Dated:** 12-02-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1509.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (DML # 000856)** **Plot No. 35-A, Small Industrial Estate, Taxila**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (DML # 000856)** **Plot No. 35-A, Small Industrial Estate, Taxila**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29853 Dated: 21-10-2022
	Details of fee submitted	PKR 30,000/-: 18-10-2022 (Slip # 57748356596)
	The proposed proprietary name / brand name	Ginza-G Gel
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of gel contains: Cindamycin Phosphate equivalent to Clindamycin …….… 12 mg (*1.2% w/w)* Tretinoin ……. 0.25 mg *(0.025% w/w)*
	Pharmacotherapeutic Group of (API)	Antibiotics / retinoid
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	20 gram tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Cleret Gel by Tabros

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Please submit section approval letter issued by Licensing Division for manufacturing facility of Gel in your firm.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer (clindamycin phosphate & Tretinoin) issued by regulatory authority of country of origin and should be valid till date.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1510.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284)** **29-30 Sector 27 Korangi Industrial Area** **Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284)** **29-30 Sector 27 Korangi Industrial Area** **Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29753 Dated: 20-10-2022
	Details of fee submitted	PKR 30,000/-: 18-10-2022 (Slip # 98081449153)
	The proposed proprietary name / brand name	Fluvi DPI powder 100 mcg + 25 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-dispensed dose contains: Fluticasone Furoate ……..… 100 mcg Vilanterol (as trifenatate) …… 25 mcg Each single inhalation contains delivered dose of Fluticasone Furoate ……..… 92 mcg Vilanterol …… 22 mcg
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airways diseases, adrenergics in combination with corticosteroids
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	30's pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Breo Ellipta
	For generic drugs (me-too status)	Relvar Ellipta by GSK

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturers (Futicasone furoate & Vilanterol) issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.2	Please clarify that your formulation contains powder for inhalation enclosed in a HPMC Capsule while the reference product is not enclosed in capsule.	Formulation already allowed in capsules by DRAP in previous meetings.
	Please also clarify that reference product administration is through a mouth piece while there is no information of administration of your formulation.	Frm submitted the details of administration of the product.
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1511.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29334 Dated: 17-10-2022
	Details of fee submitted	PKR 30,000/-: 18-10-2022 (Slip # 172272208590)

	The proposed proprietary name / brand name	Fluvi DPI capsule 200 mcg + 25 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-dispensed dose contains: Fluticasone Furoate ……..… 200 mcg Vilanterol (as trifenatate) …… 25 mcg Each single inhalation contains delivered dose of Fluticasone Furoate ……..… 184 mcg Vilanterol …… 22 mcg
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airways diseases, adrenergics in combination with corticosteroids
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	30's pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Breo Ellipta
	For generic drugs (me-too status)	Relvar Ellipta by GSK

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturers (Futicasone furoate & Vilanterol) issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.2	Please clarify that your formulation contains powder for inhalation enclosed in a HPMC Capsule while the reference product is not enclosed in capsule.	Formulation already allowed in capsules by DRAP in previous meetings.
	Please also clarify that reference product administration is through a mouth piece while there is no information of administration of your formulation.	Frm submitted the details of administration of the product.
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1512.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29754 Dated: 20-10-2022
	Details of fee submitted	PKR 75,000/-: 06-10-2022 (Slip # 248911933914)
	The proposed proprietary name / brand name	Flutika DPI capsule 100 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-dispensed dose contains: Fluticasone Furoate ……..… 100 mcg

		Each single inhalation contains delivered dose of Fluticasone Furoate …….… 90 mcg
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airways diseases, corticosteroids
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	30's pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Breo Ellipta
	For generic drugs (me-too status)	Relvar Ellipta by GSK

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturers (Futicasone furoate & Vilanterol) issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.2	Please clarify that your formulation contains powder for inhalation enclosed in a HPMC Capsule while the reference product is not enclosed in capsule.	Formulation already allowed in capsules by DRAP in previous meetings.
	Please also clarify that reference product administration is through a mouth piece while there is no information of administration of your formulation.	Frm submitted the details of administration of the product.
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1513.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Relizon Pharmaceuticals. (DML # 000875) Plot 118, Sunder Industrial estate, Lahore.**
	Name, address of Manufacturing site.	**M/s Relizon Pharmaceuticals. (DML # 000875) Plot 118, Sunder Industrial estate, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29099 Dated: 13-10-2022
	Details of fee submitted	PKR 75,000/-: 30-09-2022 (Slip # 2717880360)
	The proposed proprietary name / brand name	Capsule Durel 60 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Duloxetine HCl enteric coated pellets…… 60 mg
	Pharmacotherapeutic Group of (API)	SNRIs
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5's,10's,14's,28's & 30s (ALU/PVC Blisters)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation

	For generic drugs (me-too status)	Dulosoft capsule by Barrett Hodgson

Evaluation by DD-PE&R:

Section	Observations
3.2.P.8	Please submit documents for procurement of API. Please perform dissolution test as per methods available in official monograph of USP Pharmacopeia and submit chromatograms , calculation sheets and raw data .

Decision: registration board deferred the case for submission of reply to the above cited shortcomings within six months.

Item No. 02: New License / Section

1514.	NEW SECTION THE CENTRAL LICENSING BOARD IN ITS 289TH MEETING HELD ON 23RD FEBRUARY, 2023 HAS CONSIDERED AND APPROVED THE GRANT OF ADDITIONAL SECTION OF DRY POWDER VIAL INJECTION (CEPHALOSPORIN) FOR DML # 000933 (FORMULATION)	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	**M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.**
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER** ☐ **IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: 5BH-V4D-M1P2 DATED: 24-04-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 22-12-2023 (SLIP # 9219780181)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	ASTOZIME POWDER FOR INJECTION 250MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(POWDER FOR RECONSTITUTION)* CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME ……. 250 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**CEPHALOSPORINS**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**15 MLCLEAR GLASS VIAL USP-TYPE III**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**FORTUM INJECTION**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS

3.2.P.8	**PLEASE SUBMIT DRAP CLEARANCE DOCUMENTS FOR PROCUREMENT OF API.**	**SUBMITTED**
	PLEASE SUBMIT 06TH MONTH STABILITY STUDY DATA FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS.	**SUBMITTED**

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**.

1515.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER** ☐ **IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: 2PA-PL5-MUTG DATED: 29-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 22-12-2023 (SLIP # 47850282)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	ASTOZIME POWDER FOR INJECTION 500MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(POWDER FOR RECONSTITUTION)*** **CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME ……. 500 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**CEPHALOSPORIN**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**15 MLCLEAR GLASS VIAL USP-TYPE III**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**FORTUM INJECTION**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
3.2.P.8	**PLEASE SUBMIT DRAP CLEARANCE DOCUMENTS FOR PROCUREMENT OF API.**	**SUBMITTED**

	PLEASE SUBMIT 06TH MONTH STABILITY STUDY DATA FOR BOTH ACCELERATED AND REAL TIME CLOIMATIC CONDITIONS.	**SUBMITTED**

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1516.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S GETZ PHARMA (PVT.) LTD. - (UNIT I) (DML # 000933) PLOT NO. 1, SECTOR 25, KORANGI INDUSTRIAL AREA KARACHI.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: EYJ-37X-H67Q DATED: 29-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 22-12-2023 (SLIP # 429136722444)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	ASTOZIME POWDER FOR INJECTION 1000MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(POWDER FOR RECONSTITUTION)*** **CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME ……. 1000 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**CEPHALOSPORIN**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**15 MLCLEAR GLASS VIAL USP-TYPE III**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**FORTUM INJECTION**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
3.2.P.8	**PLEASE SUBMIT DRAP CLEARANCE DOCUMENTS FOR PROCUREMENT OF API.**	**SUBMITTED**
	PLEASE SUBMIT 06TH MONTH STABILITY STUDY DATA FOR BOTH ACCELERATED AND REAL TIME CLOIMATIC CONDITIONS.	**SUBMITTED**

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1517.	NEW SECTION THE CENTRAL LICENSING BOARD IN ITS 296TH MEETING HELD ON 02ND APRIL, 2024 HAS CONSIDERED AND APPROVED THE RENEWAL OF DML # 000655 (FORMULATION) ALONG WITH GRANT OF ADDITIONAL SECTIONS INCLUDING "LIQUID VIAL SECTION (GENERAL) SVP" "TABLET SECTION (HORMONAL) STEROIDAL"	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: HYL-RTB-3Y7N DATED: 22-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 02-05-2024 (SLIP # 1229093745)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	DILOZEN SOLUTION FOR INFUSION 2 MG/ML. (200MG/100ML)
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML OF SOLUTION FOR INFUSION CONTAINS:** **LINEZOLID ……...… 2 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTI BACTERIALS (OXAZOLIDINONES.)**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE I GLASS VIAL OF 100 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**HILID SOLUTION FROM HILTON PHARMA**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	REPLY OF THE FIRM
1.3.4	**PLEASE SUBMIT SECTION APPROVAL LETTER ISSUED BY SECRETARY CENTRAL LICENSINIG BOARD FOR**	**SUBMITTED**

	MANUFACTURING FACILITY OF THE FIRM FOR LINEZOLID INJECTION.	
3.2.P.8	**PLEASE CLARIFY THE NATURE OF PRIMARY CONTAINER OF YOUR DRUG PRODUCT IS USP TYPE I GLASS VIAL OR MULTILAYERED POLYOLEFINE FILM INFUSION BAGS (EXCEL OR FREEFLEX) SEALED INSIDE A FOIL LAMINATE OVERWRAP?**	**IT WAS A TYPO-ERROR. WE ARE USING GLASS VIAL TYPE I AS PRIMARY CONTAINER OF DRUG PRODUCT.**
	PLEASE CLARIFY THAT WHY DRAP CLEARANCE DOCUMENTS FOR ACTIVE INGREDIENT LINEZOLID OF WIMITS PHARMACEUTICAL HAS BEEN SUBMITTED?	**MATERIAL LOAN**

Decision: approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1518.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: R1Z-DSG-YRVS DATED: 27-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 02-05-2024 (SLIP # 835856414)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	TABLET LEVONOR 0.75 MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH TABLET CONTAINS: LEVONORGESTREL ……. 0.75 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, EMERGENCY CONTRACEPTIVES**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**AS PER SRO**
	PROPOSED UNIT PRICE	**AS PER SRO**

	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**EMKIT BY ZAFA**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	REPLY OF THE FIRM
3.2.P.2	**PLEASE MENTION THE CRITICAL PROCESS PARAMETERS AND QUALITY ATTRIBUTES NECESSARY TO FOCUS DURING MANUFACTURING OF TABLETS.**	**PARTICLE SIZE DISTRIBUTION CONTROLLED BY API MANUFACTURER.**
	PLEASE EXPLAIN THE PROCEDURE OF MANUFACTURING FOR CONFIRMATION OF GOOD FLOW CHARACTERISTICS AND GOOD UNIFORMITY OF FORMULATION.	**SUBMITTED**
	SINCE THE DRUG PRODUCT CONSISTS OF LESS THAN 2% ACTIVE SUBSTANCE, PLEASE SUBMIT SOP AND RESULTS OF IN PROCESS TESTS AND PARAMETERS ADOPTED FOR QUALITY BY DESIGN SO THAT MANUFACTURING PROCESS CONFIRMS THAT EVERY UNIT OF PRODUCT POSSESS EXACTLY THE SAME AMOUNT OF THE ACTIVE INGREDIENT?	**CONTENT UNIFORMITY TEST SOP SUBMITTED** **INPROCESS TEST SUBMITTED**
3.2. P.5.2	**PLEASE SUBMIT BATCH ANALYSIS REPORT OF THREE BATCHES WHICH MUST CONTAIN RESULTS ALONG WITH CHROMATOGRAMS, RAW DATA, CALCULATION SHEETS FOR CONTENT UNIFORMITY TEST, ASSAY OF API IN DRUG PRODUCT, DISSLOTION TEST WITH RELVANT CHROMATOGRAMS.**	**SUBMITTED**
3.2.P.8	**PLEASE SUBMIT DRAP CLEARANCE DOCUMENTS FOR ACTIVE INGREDIENT PROCURED BY HANSEL PHARMA.**	**SUBMITTED**

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1519.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER**

		☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: UB2-AQ4-6SNM DATED: 27-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 12-12-2023 (SLIP # 744031884348)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	TABLET LEVONOR 1.5 MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH TABLET CONTAINS: LEVONORGESTREL ……. 1.5 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, EMERGENCY CONTRACEPTIVES**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**AS PER SRO**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**EMKIT BY ZAFA**

EVALUATION BY DD-PE&R:

Section	Observations	Reply of the firm
3.2.p.2	Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets.	Particle size distribution controlled by api manufacturer.
	Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation.	Submitted
	Since the drug product consists of less than 2% active substance, please submit sop and results of in process tests and parameters adopted for quality by design so that manufacturing process confirms that every unit of product possess exactly the same amount of the active ingredient?	Content uniformity test Sop submitted Inprocess test submitted
3.2. P.5.2	Please submit batch analysis report of three batches which must contain results along with chromatograms, raw data, calculation sheets for content uniformity test, assay of api in drug product, disslotion test with relvant chromatograms.	Submitted
3.2.p.8	Please submit drap clearance documents for active ingredient procured by hansel pharma.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1520.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S SKYWIN PHARMACEUTICAL (DML # 000971) PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: 2LY-37D-DD4P DATED: 29-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 13-12-2023 (SLIP # 35799988839)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	TABLET D-GEST 10 MG
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE ……. 10 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**GENITO URINARY SYSTEM AND SEX HORMONES.**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**AS PER SRO**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**DUPHASTON 10 MG FILM-COATED TABLETS**
EVALUATION BY DD-PE&R		
Decision: approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1521.	NEW SECTTION THE CENTRAL LICENSING BOARD IN ITS 296TH MEETING HELD ON 02ND APRIL, 2024 HAS CONSIDERED AND APPROVED THE RENEWAL OF DML # 000655 (FORMULATION) ALONG WITH GRANT OF ADDITIONAL SECTIONS INCLUDING "INJECTABLE (AMPOULE/VIAL) SVP (LYOPHILIZED / LIQUID) GENERAL"	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.

	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK DEZ-XHU-ZNN9: 22-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 13-05-2024 (SLIP # 774387615)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	CLEARVUE 50ML INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML CONTAINS:** **IOHEXOL 755 MG EQUIVALENT TO IODINE …… 350 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**CONTRAST MEDIA IV**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE I GLASS VIAL OF 50 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**OMNIPAQUE® USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**OMNIPAQUE® LOCAL REGISTRATION (IMPORT)**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
1.5.2	PLEASE MENTION IN THE LABEL CLAIM QUANTITY OF IOHEXOL EQUIVALENT TO QUANTITY OF IODINE.	SUBMITTED
3.2.S.7	PLEASE SUBMIT STABILITY DATA OF API AT CLIMATIC CONDITION OF ZONE IV REQUIRED FOR PAKISTAN.	SUBMITTED
3.2.P.8	PLEASE SUBMIT COMPLETE SIX-MONTH STABILITY DATA OF THREE BATCHES FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS ALONG WITH STABILITY SHEETS / CALCULATION SHEETS AND RAW DATA.	SUBMITTED
	PLEASE SUBMIT COA OF API USED IN MANUFACTURING OF THE STABILITY BATCHES.	SUBMITTED
	PLEASE JUSTIFY THAT HOW 50 VIALS ARE ENOUGH FOR CONDUCTING 2 YEARS STABILITY STUDIES FOR BOTH ACCELERATED AND REAL TIME CONDITIONS?	SUBMITTED

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1522.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK 2PE-36B-MRAV: 24-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 03-04-2024 (SLIP # 0124643533)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	CLEARVUE 100ML INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML CONTAINS:** **IOHEXOL … 350 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**CONTRAST MEDIA IV**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE I GLASS VIAL OF 100 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**OMNIPAQUE® USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**OMNIPAQUE® LOCAL REGISTRATION (IMPORT)**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
1.5.2	PLEASE MENTION IN THE LABEL CLAIM QUANTITY OF IOHEXOL EQUIVALENT TO QUANTITY OF IODINE.	SUBMITTED
3.2.S.7	PLEASE SUBMIT STABILITY DATA OF API AT CLIMATIC CONDITION OF ZONE IV REQUIRED FOR PAKISTAN.	SUBMITTED
3.2.P.8	PLEASE SUBMIT COMPLETE SIX-MONTH STABILITY DATA OF THREE BATCHES FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS ALONG WITH STABILITY SHEETS / CALCULATION SHEETS AND RAW DATA.	SUBMITTED
	PLEASE SUBMIT COA OF API USED IN MANUFACTURING OF THE STABILITY BATCHES.	SUBMITTED

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1523.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK E6T-ZAT-56JQ: 21-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 13-03-2024 (SLIP # 1828559044)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	TIROBAN INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 15 ML CONTAINS:** **TIROFIBAN HCL 4.215 MG EQUIVALENT TO TIROFIBAN ……. 3.75 MG *(250 MCG/ML)***
	PHARMACOTHERAPEUTIC GROUP OF (API)	**PLATELET AGGREGATION INHIBITOR**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE I GLASS VIAL OF 30 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**AGGRASTAT® USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**AGGRASTAT® LOCAL REGISTRATION (IMPORT)**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
1.5.2	PLEASE MENTION IN THE LABEL CLAIM QUANTITY OF SALT EQUIVALENT TO QUANTITY OF BASE.	SUBMITTED
3.2.S.7	PLEASE SUBMIT STABILITY DATA OF API AT CLIMATIC CONDITION OF ZONE IV REQUIRED FOR PAKISTAN.	SUBMITTED
3.2.P.8	PLEASE SUBMIT COMPLETE SIX-MONTH STABILITY DATA OF THREE BATCHES FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS ALONG WITH STABILITY SHEETS / CALCULATION SHEETS AND RAW DATA.	SUBMITTED
	PLEASE SUBMIT COA OF API USED IN MANUFACTURING OF THE STABILITY BATCHES.	SUBMITTED

DECISION: APPROVED WITH INNOVATOR'S SPECIFICATIONS.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1524.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER** ☐ **IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK DW3-EMP-5UW9: 21-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 19-01-2024 (SLIP # 698621889876)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**ONDAN 4MG INJECTION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 2 ML CONTAINS:** **ONDANSETRON HCL DIHYDRATE EQUIVALENT TO ONDANSETRON……. 4 MG *(2 MG/ML)***
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTI-EMETIC DRUG**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**1'S & 5'S. 2ML USP TYPE 1 GLASS AMPOULE**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ONSET INJECTION**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
3.2.S.7	PLEASE SUBMIT STABILITY DATA OF API AT CLIMATIC CONDITION OF ZONE IV REQUIRED FOR PAKISTAN.	SUBMITTED

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1525.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER**

		☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK LWT-4AL-SMXL: 21-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 19-01-2024 (SLIP # 117223127)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**ONDAN 8MG INJECTION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 4 ML CONTAINS:** **ONDANSETRON HCL DIHYDRATE EQUIVALENT TO ONDANSETRON……. 8MG *(2 MG/ML)***
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTI-EMETIC DRUG**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**1'S & 5'S. 5ML USP TYPE 1 GLASS AMPOULE**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ONSET INJECTION**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1526.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK J34-NS6-JBN9: 21-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 19-01-2024 (SLIP # 889717609163)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**FERIUM 500 MG INJECTION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE	**EACH VIAL (10 ML) CONTAINS:**

	PHARMACEUTICAL INGREDIENT (API) PER UNIT	**FERRIC CARBOXYMALTOSE EQUIVALENT TO ELEMENTAL IRON……. 500 MG (50MG/ML)**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIANEMIC DRUG**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATION**
	PROPOSED PACK SIZE	**10ML USP TYPE 1 GLASS VIAL**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**FERINJECT INJECTION IMPORT BY OBS**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED WITH INNOVATOR'S SPECIFICATIONS. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1527.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **TRACK RSU-Q25-PN6B: 21-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 03-01-2024 (SLIP # 339135450)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**VORIF 200MG INFUSION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL (30 ML) CONTAINS:** ***(LYOPHILIZED POWDER FOR INFUSION)*** **VORICONAZOLE ……. 200 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**AZOLE AGENT (ANTIFUNGAL)**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATION**
	PROPOSED PACK SIZE	**30ML USP TYPE 1 CLEAR GLASS VIAL**
	PROPOSED UNIT PRICE	**AS PER SRO**

	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**NORIC 200 MG INFUSION BY MTI (MEDICAL) PVT. LTD.**

EVALUATION BY DD-PE&R:

DECISION: APPROVED WITH INNOVATOR'S SPECIFICATIONS.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1528.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: DY. NO. 14384** **DATED: 08-06-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 25-05-2023 (SLIP # 23137622)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**TRAMIX INJECTION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 2 ML CONTAINS:** **TRAMADOL HCL ……. 100 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**OPIOID ANALGESIC**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATION**
	PROPOSED PACK SIZE	**2ML USP TYPE 1 CLEAR GLASS AMPOULE**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**TRAMAL INJECTION BY SEARLE**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
1.6.5	PLEASE SUBMIT GMP CERTIFICATE OF API SUPPLIER WHICH SHOULD BE ISSUED BY REGULATORY AUTHORITY OF COUTRY OF ORIGIN AND SHOUD BE VALID TILL DATE.	SUBMITTED
3.2.P.8	PLEASE SUBMIT COA OF API USED IN MANUFACTURING OF THESE STABILITY BATCHES	SUBMITTED

	PLEASE SUBMIT COMPLETE STABILITY DATA OF 06TH MONTH INTERVAL FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS.	SUBMITTED

DECISION: APPROVED WITH INNOVATOR'S SPECIFICATIONS.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1529.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 9818 DATED: 12-04-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 15-02-2023 (SLIP # 5469519503)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**ACYCLEX 250 MG INFUSION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(LYOPHILIZED POWDER FOR INFUSION)*** **ACICLOVIR ……. 250 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIVIRUS AGENT.**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**30ML USP TYPE 1 CLEAR GLASS VIAL**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ACLOVIR BY GENIX**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	REPLY OF THE FIRM
1.6.5	PLEASE SUBMIT GMP CERTIFICATE OF API SUPPLIER WHICH SHOULD BE ISSUED BY REGULATORY AUTHORITY OF COUTRY OF ORIGIN AND SHOUD BE VALID TILL DATE.	SUBMITTED
3.2.P.2	PLEASE PROVIDE DETAILS REGARDING LYOPHILIZATION CYCLE AND VALIDATION OF DURATION OF EACH CYCLE.	SUBMITTED

	PLEASE PROVIDE MECHANISM OF FILLING AND TRANSFER OF PARTIALLY STOPPERED VIAL TO LYOPHILIZER.	THE PRODUCTS FILLED UNDER CASS A, PARTIALLY STOPPERED THENBY MAINTAINING CLASS A IALS MOVED TO LYOPHILZER FOR FREEZE DRYING.

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1530.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 9818 DATED: 12-04-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 16-02-2023 (SLIP # 2818316615)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**ACYCLEX 500 MG INFUSION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(LYOPHILIZED POWDER FOR INFUSION)*** **ACICLOVIR ……. 500 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIVIRUS AGENT.**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**30ML USP TYPE 1 CLEAR GLASS VIAL**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ACLOVIR BY GENIX**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	REPLY OF THE FIRM
MODULE I	PLEASE SUBMIT MODULE I AS PER THE FORMULATION APPLIED.	SUBMITTED
1.6.5	PLEASE SUBMIT GMP CERTIFICATE OF API SUPPLIER WHICH SHOULD BE ISSUED BY REGULATORY AUTHORITY OF COUTRY OF ORIGIN AND SHOUD BE VALID TILL DATE.	SUBMITTED

3.2.P.2	PLEASE PROVIDE DETAILS REGARDING LYOPHILIZATION CYCLE AND VALIDATION OF DURATION OF EACH CYCLE.	SUBMITTED
	PLEASE PROVIDE MECHANISM OF FILLING AND TRANSFER OF PARTIALLY STOPPERED VIAL TO LYOPHILIZER.	THE PRODUCTS FILLED UNDER CASS A, PARTIALLY STOPPERED THENBY MAINTAINING CLASS A IALS MOVED TO LYOPHILZER FOR FREEZE DRYING.
3.2.P.8	PLEASE SUBMIT COMPLETE STABILITY RESULTS FOR ACYCLEX 500 MG INJECTION FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS.	SUBMITTED

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1531.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 9818 DATED: 12-04-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 16-02-2023 (SLIP # 2818316615)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**AZOBAR 500 MG INFUSION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH VIAL CONTAINS: *(LYOPHILIZED POWDER FOR INFUSION)*** **AZITHROMYCIN DIHYDRATE EQUIVALENT TO** **AZITHROMYCIN ……. 500 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**MACROLIDES**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**30ML USP TYPE 1 CLEAR GLASS VIAL**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**

	FOR GENERIC DRUGS (ME-TOO STATUS)	**ACLOVIR BY GENIX**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	REPLY OF THE FIRM
1.6.5	PLEASE SUBMIT GMP CERTIFICATE OF API SUPPLIER WHICH SHOULD BE ISSUED BY REGULATORY AUTHORITY OF COUTRY OF ORIGIN AND SHOUD BE VALID TILL DATE.	SUBMITTED
3.2.P.2	PLEASE PROVIDE DETAILS REGARDING LYOPHILIZATION CYCLE AND VALIDATION OF DURATION OF EACH CYCLE.	SUBMITTED
	PLEASE PROVIDE MECHANISM OF FILLING AND TRANSFER OF PARTIALLY STOPPERED VIAL TO LYOPHILIZER.	THE PRODUCTS FILLED UNDER CASS A, PARTIALLY STOPPERED THENBY MAINTAINING CLASS A IALS MOVED TO LYOPHILZER FOR FREEZE DRYING.
3.2.P.8	PLEASE CLARIFY THAT WHY ANALYTICAL METHOD HAS NOT BEEN VALIDATED PROPERLY TO REMOVE THE NEGATIVE PEAKS (DRIFTS) IN THE CHROMATOGRAMS OF SAMPLE OF DRUG PRODUCTS? THE BASELINE IS ALSO NOT STABLE IN YOUR CHROMATOGRAMS ?	FIRM HAS EXPLAINED THAT NEGATIVE PEAK WAS ALSO OBSERVED IN BLNK INJECTION. AS IT IS A PHARMACOPEIAL METHOD THAT'S WHY WE HAVE CONFIRMED THE DISTANCE BETWEEN PEAK OF INTEREST AND NEGATIVE PEAK.

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1532.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 26951 DATED: 14-11-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 16-06-2023 (SLIP # 7561146486)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**KETRO INJECTION**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML CONTAINS:** **KETOROLAC TROMETHAMINE …….** **30 MG**

	PHARMACOTHERAPEUTIC GROUP OF (API)	**NSAID**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE 1 CLEAR GLASS AMPOULE**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**TORADOL INJECTION BY MARTIN DOW MARKER**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
1.6.5	PLEASE SUBMIT GMP CERTIFICATE OF API SUPPLIER WHICH SHOULD BE ISSUED BY REGULATORY AUTHORITY OF COUTRY OF ORIGIN AND SHOUD BE VALID TILL DATE.	SUBMITTED
3.2.P.8	PLEASE SUBMIT COMPLETE STABILITY DATA FOR 06TH MONTH INTERVAL FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS OF PAKISTAN.	SUBMITTED

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1533.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 26952 DATED: 14-11-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 08-06-2023 (SLIP # 346490593912)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**STERILE WATER FOR INJECTION 5ML**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH AMPOULE CONTAINS:** **WFI ……. 5ML**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**DILUENT**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**5ML USP TYPE 1 CLEAR GLASS AMPOULE**

		(1'S, 20'S, 50'S & 100'S)
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**LOCALLY REGISTERED WFI FOR BARRETT HODGSON**

EVALUATION BY DD-PE&R:

SECTION	OBSERVATIONS	STATUS
3.2.P.8	**PLEASE SUBMIT COMPLETE STABILITY DATA FOR 06TH MONTH INTERVAL FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS OF PAKISTAN.**	**SUBMITTED**

DECISION: APPROVED.

- **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**
- **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**

1534.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S BF BIOSCIENCES LTD. (DML # 000655) 5-KM SUNDAR RAIWIND ROAD RAIWIND LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F:** **DY. NO. 26953 DATED: 14-11-2023**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 08-06-2023 (SLIP # 549702186749)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**STERILE WATER FOR INJECTION 10ML**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH AMPOULE CONTAINS:** **WFI ……. 10ML**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**DILUENT**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**10ML USP TYPE 1 CLEAR GLASS AMPOULE (1'S, 20'S, 50'S & 100'S)**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**LOCALLY REGISTERED WFI FOR BARRETT HODGSON**

EVALUATION BY DD-PE&R: SECTION 3.2.P.8	OBSERVATIONS **PLEASE SUBMIT COMPLETE STABILITY DATA FOR 06TH MONTH INTERVAL FOR BOTH ACCELERATED AND REAL TIME CLIMATIC CONDITIONS OF PAKISTAN.**	STATUS **SUBMITTED**
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1535.	NEW SECTION THE CENTRAL LICENSING BOARD IN ITS 294TH MEETING HELD ON 27TH DECEMBER 2023 HAS CONSIDERED AND APPROVED THE GRANT OF ADDITIONAL SECTION OF AMPOULE SECTION (GENERAL) FOR DML # 000300 (FORMULATION).	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	STATUS OF THE APPLICANT	☒ **MANUFACTURER** ☐ **IMPORTER** ☐ **IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: 5BH-V4D-M1P2 DATED: 24-04-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 22-12-2023 (SLIP # 9219780181)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	VEE- LOT (PHYTONADIONE 2MG/ML)
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML CONTAINS:** **PHYTONADIONE *(VITAMIN K_1)* ……. 2 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIHAEMORRHAGIS**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**1 AMP X 1ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**K-LOT INJECTION BY GT PHARMA**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED**		

STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION. • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1536.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: 5BH-V4D-M1P2 DATED: 24-04-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 22-12-2023 (SLIP # 9219780181)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	VEE- LOT (PHYTONADIONE 10MG/ML)
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH ML CONTAINS:** **PHYTONADIONE *(VITAMIN K_1)* ……. 10 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIHAEMORRHAGIS**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**1 AMP X 1ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**USFDA APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**K-LOT INJECTION BY GT PHARMA**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1537.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S VENUS PHARMA (PRIVATE) LIMITED. (DML # 000300) 23 KM MULTAN ROAD LAHORE.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER**

		☐ IMPORTER **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: X15-4NM-6N8H DATED: 30-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 18-03-2024 (SLIP # 66101184250)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	VEE-SET INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 4ML CONTAINS:** **ONDANSETRON (AS HCL) …… 8 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIEMETIC**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**5-AMP (USP TYPE I) X 4 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ONSET INJECTION BY PHARMEDICS**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1538.	NEW SECTION / LICENSE CENTRAL LICENSING BOARD IN ITS 292ND MEETING HELD ON 04TH OCTOBER 2023 APPROVED THE GRANT OF DML # 000985 (FORMULATION) INCLUDING THE MANUFACTURING FACILITY OF "GENERAL LIQUID INJECTABLE AMPOULE / VIALS"	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	MISAQ PHARMACEUTICALS PVT LTD. (DML # 000985) PLOT NO.7-B,WOVEN GARMENTS ZONE, VALUE ADDITION CITY, KHURRIANWALA-SAHIANWALA ROAD (FIEDMC)
	NAME, ADDRESS OF MANUFACTURING SITE.	MISAQ PHARMACEUTICALS PVT LTD. (DML # 000985) PLOT NO.7-B,WOVEN GARMENTS ZONE, VALUE ADDITION CITY, KHURRIANWALA-SAHIANWALA ROAD (FIEDMC)
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**

	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: X6U-SRL-2PAH DATED: 30-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 14-05-2024 (SLIP # 689930020962)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	ONDRON INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 4ML CONTAINS: ONDANSETRON (AS HCL) …… 8 MG**
	PHARMACOTHERAPEUTIC GROUP OF (API)	**ANTIEMETIC**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**USP SPECIFICATION**
	PROPOSED PACK SIZE	**5-AMP (USP TYPE I) X 4 ML**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**ONSET INJECTION BY PHARMEDICS**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		
1539.	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	MISAQ PHARMACEUTICALS PVT LTD. (DML # 000985) PLOT NO.7-B,WOVEN GARMENTS ZONE, VALUE ADDITION CITY, KHURRIANWALA-SAHIANWALA ROAD (FIEDMC)
	NAME, ADDRESS OF MANUFACTURING SITE.	MISAQ PHARMACEUTICALS PVT LTD. (DML # 000985) PLOT NO.7-B,WOVEN GARMENTS ZONE, VALUE ADDITION CITY, KHURRIANWALA-SAHIANWALA ROAD (FIEDMC)
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	APPLICATION FORM DY. NO / TRACKING ID & DATE OF SUBMISSION	**FORM 5F: TRACK ID: X6U-SRL-2PAH DATED: 30-05-2024**
	DETAILS OF FEE SUBMITTED	**PKR 30,000/-: 14-05-2024 (SLIP # 689930020962)**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	MISADOL INJECTION
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE	**EACH 2ML CONTAINS: TRAMADOL HCL …… 100 MG (50MG/ML)**

	PHARMACEUTICAL INGREDIENT (API) PER UNIT	
	PHARMACOTHERAPEUTIC GROUP OF (API)	**OPIOID ANALGESIC**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**BP SPECIFICATION**
	PROPOSED PACK SIZE	**USP TYPE I CLEAR GLASS AMPOULE 2ML X 5'S**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**MHRA UK APPROVED FORMULATION**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**TRAMAL INJECTION BY SEARLE**
EVALUATION BY DD-PE&R:		
DECISION: APPROVED. • **MANUFACTURER WILL PLACE FIRST THREE PRODUCTION BATCHES ON LONG TERM STABILITY STUDIES THROUGHOUT PROPOSED SHELF LIFE AND ON ACCELERATED STUDIES FOR SIX MONTHS AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.** • **MANUFACTURER WILL PERFORM PROCESS VALIDATION OF FIRST THREE BATCHES AS PER THE COMMITMENT SUBMITTED IN THE REGISTRATION APPLICATION.**		

Item No. 03: Export facilitation Cases:

1540.	Assistant Director (PR-I/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 29th December 2022 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Getz Pharma (Pvt.) Ltd. (DML # 000284) Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.** has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2021-2022** and requested for priority consideration of following molecule	
	NAME, ADDRESS OF APPLICANT / MARKETING AUTHORIZATION HOLDER	M/S GETZ PHARMA (PVT.) LTD. (DML # 000284) PLOT # 29-30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI.
	NAME, ADDRESS OF MANUFACTURING SITE.	M/S GETZ PHARMA (PVT.) LTD. (DML # 000284) PLOT # 29-30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI.
	STATUS OF THE APPLICANT	**☒ MANUFACTURER** **☐ IMPORTER** **☐ IS INVOLVED IN NONE OF THE ABOVE (CONTRACT GIVER)**
	GMP STATUS OF THE FIRM	**GMP CERTIFICATE ISSUED ON THE BASIS OF INSPECTION REPORT CONDUCTED ON 13TH JANUARY 2022.**
	EVIDENCE OF APPROVAL OF MANUFACTURING FACILITY	**CENTRAL LICENSING BOARD IN ITS 271ST MEETING HELD ON 12TH SEPTEMBER 2019 APPROVED THE RENEWAL OF DML INCLUDING LIQUID INJECTION VIAL (GENERAL).**
	STATUS OF APPLICATION	**☐ NEW DRUG PRODUCT (NDP)** **☒ GENERIC DRUG PRODUCT (GDP)**

	INTENDED USE OF PHARMACEUTICAL PRODUCT	**☐ DOMESTIC SALE** **☐ EXPORT SALE** **☒ DOMESTIC AND EXPORT SALES**
	DY. NO. AND DATE OF SUBMISSION	**DY. NO 31351 DATED 02-11-2022**
	DETAILS OF FEE SUBMITTED	**PKR 75,000/-: DATED 26-07-2022** **SLIP # 0026065204**
	THE PROPOSED PROPRIETARY NAME / BRAND NAME	**BRIVAGET SOLUTION FOR INJECTION 50 MG/ 5ML**
	STRENGTH / CONCENTRATION OF DRUG OF ACTIVE PHARMACEUTICAL INGREDIENT (API) PER UNIT	**EACH 5ML OF SOLUTION IN AMPOULES CONTAINS:** **BRIVARACETAM …… 50 MG**
	PHARMACO-THERAPEUTIC GROUP OF (API)	**ANTICONVULSANT ACTIVITY**
	PHARMACEUTICAL FORM OF APPLIED DRUG	**IV SOLUTION FOR INJECTION**
	REFERENCE TO FINISHED PRODUCT SPECIFICATIONS	**INNOVATOR SPECIFICATIONS**
	PROPOSED PACK SIZE	**1'S (5ML GLASS AMPOULE)**
	PROPOSED UNIT PRICE	**AS PER SRO**
	THE STATUS IN REFERENCE REGULATORY AUTHORITIES	**BRIVIACT® INJECTION, USFDA APPROVED FORMULATION.**
	FOR GENERIC DRUGS (ME-TOO STATUS)	**BRAND NAME: CUBRIVA 50MG/5ML** **MANUFACTURER: M/S GENIX**
	Name and address of API manufacturer.	**<u>Brivaracetam</u>** Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	BRAND NAME: **INJECTION BRIVLERA IV 50 MG/5ML** MANUFACTURER: **M/S UCB CANADA** TESTING PARAMETERS: **INNOVATOR SPECIFICATIONS**
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
MANUFACTURER OF API	**NAME: M/S LEE PHARMA LIMITED ADDRESS: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA STATE, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.**		
API LOT NO.	**BRIP0321020**		
DESCRIPTION OF PACK (CONTAINER CLOSURE SYSTEM)	**50MG/5ML, C CLEAR COLORLESS LIQUID, FREE FOREIGN PARTICLES, FILLED IN CLEAR GLASS AMPOULE USP TYPE-I, FURTHER PACKED IN SECONDARY CARTON.**		
STABILITY STORAGE CONDITION	**REAL TIME: 30°C ± 2°C / 65% ± 5%RH ACCELERATED: 40°C ± 2°C / 75% ± 5%RH**		
TIME PERIOD	**REAL TIME: 06 MONTHS ACCELERATED: 06 MONTHS**		
FREQUENCY	**ACCELERATED: 0, 3, 6 (MONTHS) REAL TIME: 0, 3, 6, 9, 12 (MONTHS)**		
BATCH NO.	**612DS01**	**612DS02**	**612DS03**
BATCH SIZE	**1500 AMPOULES**	**1500 AMPOULES**	**1500 AMPOULES**
MANUFACTURING DATE	**17-12-2021**	**17-12-2021**	**17-12-2021**
DATE OF INITIATION	**15-02-2022**	**15-02-2022**	**15-02-2022**
NO. OF BATCHES	**03**		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**QUANTITY: 4KG** **INVOICE: 1225/LP/2021-22** **DATED: 11-09-2021**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1541.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Setion.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29335 dated 17-10-2022
	Details of fee submitted	PKR 30,000/-: Dated 22-07-2022 Slip # 9951185656
	The proposed proprietary name / brand name	BRIVAGET Tablet 10 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 10 mg

	Pharmaco-therapeutic Group of (API)	Anticonvulsant Activity
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's & 14's Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT® 10mg Tablets, USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Brivatam 10mg Tablets Manufacturer: M/s CCL
	Name and address of API manufacturer.	Brivaracetam Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet brivace 10 mg Manufacturer: M/s Hilton Pharma Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.
API Lot No.	RIP0321020
Description of Pack (Container closure system)	10mg, orange colored, round shaped biconvex film coated tablet, plain on both sides, packed in ALU-ALU Blister, further packed in secondary carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	606DS01	606DS02	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	25-02-2022	25-02-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 4kg Invoice: 1225/LP/2021-22 Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

		along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1542.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Setion.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28653 dated 10-10-2022
	Details of fee submitted	PKR 30,000/-: Dated 26-07-2022 Slip # 78983042
	The proposed proprietary name / brand name	BRIVAGET Tablet 25 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 25 mg
	Pharmaco-therapeutic Group of (API)	Anticonvulsant Activity
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10’s & 14’s Tablets
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	BRIVIACT® 25mg Tablets, USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Cubriva 25mg Tablets Manufacturer: M/s Genix
	Name and address of API manufacturer.	Brivaracetam Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet brivatam 25 mg Manufacturer: M/s CCL Pharmaceuticals Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.

API Lot No.	RIP0321020		
Description of Pack (Container closure system)	25mg, Dark orange colored, round shaped film coated tablet, plain on both sides, packed in ALU-ALU Blister, further packed in secondary carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	607DS01	607DS02	607DS03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	31-12-2021	31-12-2021	31-12-2021
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 4kg Invoice: 1225/LP/2021-22 Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1543.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28654 dated 10-10-2022
	Details of fee submitted	PKR 30,000/-: Dated 22-07-2022 Slip # 5221470225
	The proposed proprietary name / brand name	BRIVAGET Tablet 50 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 50 mg
	Pharmaco-therapeutic Group of (API)	Anticonvulsant Activity
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's & 14's Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT® 50mg Tablets, USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Cubriva 50mg Tablets Manufacturer: M/s Genix
	Name and address of API manufacturer.	<u>Brivaracetam</u> Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Brivatam 50 mg Manufacturer: M/s CCL Pharmaceuticals Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.		
API Lot No.	RIP0321020		
Description of Pack (Container closure system)	50mg, Dark orange colored, round shaped film coated tablet, plain on both sides, packed in ALU-ALU Blister, further packed in secondary carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	616DS01	616DS02	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	31-12-2021	31-12-2021	
Date of Initiation	26-01-2022	26-01-2022	
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 4kg Invoice: 1225/LP/2021-22 Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1544.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 31352 dated 02-11-2022
	Details of fee submitted	PKR 30,000/-: Dated 22-07-2022 Slip # 65968156
	The proposed proprietary name / brand name	BRIVAGET Tablet 75 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 75 mg
	Pharmaco-therapeutic Group of (API)	Anticonvulsant Activity

	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's & 14's Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT® 75mg Tablets, USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Cubriva 75mg Tablets Manufacturer: M/s Genix
	Name and address of API manufacturer.	Brivaracetam Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Brivatam 75 mg Manufacturer: M/s CCL Pharmaceuticals Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.		
API Lot No.	RIP0321020		
Description of Pack (Container closure system)	75mg, Dark orange colored, round shaped film coated tablet, plain on both sides, packed in ALU-ALU Blister, further packed in secondary carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	614DS01	614DS02	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	31-12-2021	31-12-2021	
Date of Initiation	26-01-2022	26-01-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 4kg Invoice: 1225/LP/2021-22 Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1545.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**

	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28773 dated 11-10-2022
	Details of fee submitted	PKR 30,000/-: Dated 22-07-2022 Slip # 4651358869
	The proposed proprietary name / brand name	BRIVAGET Tablet 100 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …… 100 mg
	Pharmaco-therapeutic Group of (API)	Anticonvulsant Activity
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's & 14's Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT® 100 mg Tablets, USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Cubriva 100mg Tablets Manufacturer: M/s Genix
	Name and address of API manufacturer.	<u>Brivaracetam</u> Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Brivatam 100 mg Manufacturer: M/s CCL Pharmaceuticals Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.		
API Lot No.	RIP0321020		
Description of Pack (Container closure system)	50mg, Dark orange colored, oblong shaped film coated tablet, plain on both sides, packed in ALU-ALU Blister, further packed in secondary carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	615DS01	615DS02	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	31-12-2021	31-12-2021	
Date of Initiation	26-01-2022	26-01-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 4kg Invoice: 1225/LP/2021-22 Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1546.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 19775 dated 09-08-2023
	Details of fee submitted	PKR 75,000/-: Dated 20-06-2023 Slip # 9269388746
	The proposed proprietary name / brand name	Bemiget Tablet 180 mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic Acid…… 180mg
	Pharmaco-therapeutic Group of (API)	Lipid modifying agents ATC code: C10AX15
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's, 20's & 30's Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nilemdo® Tablets, MHRA approved formulation.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: M/s Optimus Drugs Private Limited Address: Unit I, Sy No. 239 & 240, Dothingudem Village, B.Pochampally Mandal, Yadadri Bhuvanagiri District, Pincode 508284, Telangana State, India. GMP validity: 20-05-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Naxletol 180 mg Manufacturer: M/s Esperion USA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile**

		Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Optimus Drugs Private Limited Address: Unit I, Sy No. 239 & 240, Dothingudem Village, B.Pochampally Mandal, Yadadri Bhuvanagiri District, Pincode 508284, Telangana State, India.		
API Lot No.	BEEC100722		
Description of Pack (Container closure system)	180 mg, white colored, round shape, film coated tablet, plain on both sides, packed in ALU-PVC blister, further packed in secondary carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	643DS01	643DS02	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	20-10-2022	21-10-2022	
Date of Initiation	05-12-2022	05-12-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 7.5 kg Invoice: 2223OD148/EXP Dated: 13-07-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1547.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 271st meeting held on 12th September 2019 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7913 dated 20-03-2023
	Details of fee submitted	PKR 75,000/-: Dated 06-01-2023 Slip # 0827686730
	The proposed proprietary name / brand name	Rupadin Tablets 10 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Rupatadine (as fumarate) …… 10mg
	Pharmaco-therapeutic Group of (API)	Antihistamines for systemic use
	Pharmaceutical form of applied drug	Oral Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 11906/0007)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA. GMP validity: 13-09-2025

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Rupall 10 mg Manufacturer: M/s Medexus Pharmaceuticals Spain Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s LEE Pharma Limited Address: SY NO. 10/G-1, GADDAPOTHARAM (V), JINNARAM (M), SANGAREDDY (D)TELANGANA State, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, INDIA.		
API Lot No.	RDP21002		
Description of Pack (Container closure system)	10 mg, white colored, round shaped tablet, plain on both sides, packed in ALU-PVDC Blister.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	603DS01	603DS02	

Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	30-12-2021	30-12-2021	
Date of Initiation	11-02-2022	11-02-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 500 grams Invoice: L05/LP/2021-22 Dated: 25-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 29th December 2022 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Surge Laboratories (Private) Limited (DML # 000484)** 10th km, Faisalabad Road, Bikhi District, Sheikhupura, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2020-2021** and requested for priority consideration of following molecule.

1548.	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories (Private) Limited (DML # 000484) 10th km, Faisalabad Road, Bikhi District, Sheikhupura .**
	Name, address of Manufacturing site.	**M/s Surge Laboratories (Private) Limited (DML # 000484) 10th km, Faisalabad Road, Bikhi District, Sheikhupura .**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 05-10-2021
	Evidence of approval of manufacturing facility	Central Licensing Board in its 284th meeting held on 16th December 2021 approved the renewal of DML including Liquid Injectable General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33132 dated 18-11-2022
	Details of fee submitted	PKR 30,000/-: Dated 18-10-2022 Slip # 4077073527
	The proposed proprietary name / brand name	Zolastal IV infusion 4 mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml glass vial Contains: Zoledronic acid monohydrate equivalent to Zoledronic Aacid …… 4 mg
	Pharmaco-therapeutic Group of (API)	For treatment of bone disease
	Pharmaceutical form of applied drug	100 ml glass vial as a sterile liquid ready to use solution for intravenous infusion in a single pack.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	100 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zometa®, USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Zometa Manufacturer: Novartis Pharma (Pak) Ltd Reg. # 072551
	Name and address of API manufacturer.	Name: M/s Ultratech India Ltd. Address: New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad, Maharashtra, India. GMP Validity: 20-03-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Zometa IV infusion Manufacturer: Novartis Pharma Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Ultratech India Ltd. Address: New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad, Maharashtra, India.		
API Lot No.	UT2181007		
Description of Pack (Container closure system)	100 ml clear glass vial moduled USP Type-II		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	ZAI-4-003	ZAI-4-004	ZAI-4-005
Batch Size	20 Vials	20 Vials	20 Vials
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	04-2020	04-2020	04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 30 gm Clearance Date: 30-11-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 20th July 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Shaigan Pharmaceuticals Private Limited (DML # 000333) 14-km Adyala Road, Post Office Dahgal, Rawalpindi**, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2022-2023** and requested for priority consideration of following molecule.

1549.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Private Limited. (DML # 000333) 14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceuticals Private Limited. (DML # 000333) 14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04-11-2021
	Evidence of approval of manufacturing facility	Central Licensing Board in its 272nd meeting held on 17th October 2019 approved the renewal of DML including Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13522 dated 31-05-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-04-2023 (Slip # 8958333272)
	The proposed proprietary name / brand name	Emdagan Plus XR Tablet 5/1000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Extended release core tablet of Metformin HCl ……. 1000 mg With coating of immediate release drug substance Empagliflozin ……. 5 mg
	Pharmaco-therapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Oral film coated extended release tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR® tablet , USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Erli Plus XR Tablet Manufacturer: PharmEvo

	Name and address of API manufacturer.	Empagliflozin Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. Metformin HCl Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH Metformin HCl Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Synjardy XR 5/1000 Manufacturer: Boehringer Ingelheim Limited Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		Empagliflozin Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. Metformin HCl Name: M/s Smruthi Organics Limited

	Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.		
API Lot No.	Empagliflozin	Metformin HCl	
	EPG-201901001	MFH-110/18	
Description of Pack (Container closure system)	White colored labeled cardboard box contains pink color, oblong biconvex plain on both side film coated tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		

Batch No.	T-01	T-02	T-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin Quantity: 2 kg Clearance Date: 07-03-2019 Metformin HCl Quantity: 2000 kg Clearance Date: 04-03-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of both API manufacturers (Empagliflozin & Metformin HCl) issued by regulatory authority of the country and should be in force till date.	Submitted
1.3.4	Please submit section approval letter of Tablet (General) Section approved by Central Licensing Board.	Submitted
3.2.P.5	Please specify the tests performed for solution of coating containing drug substance Empaglifozin.	Submitted

Decision: approved with innovator specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1550.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Private Limited.** **(DML # 000333)** **14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceuticals Private Limited.** **(DML # 000333)** **14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04-11-2021
	Evidence of approval of manufacturing facility	Central Licensing Board in its 272nd meeting held on 17th October 2019 approved the renewal of DML including Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13523 dated 31-05-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-04-2023 Slip # 446765976528
	The proposed proprietary name / brand name	Emdagan Plus XR Tablet 10/1000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Extended release core tablet of Metformin HCl ……. 1000 mg With coating of immediate release drug substance Empagliflozin ……. 10 mg
	Pharmaco-therapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Oral film coated extended release tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR® tablet , USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Erli Plus XR Tablet Manufacturer: PharmEvo
	Name and address of API manufacturer.	<u>Empagliflozin</u> Name: M/s Jiangsu Yongan Pharmaceutical.

		Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. Metformin HCl Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH Metformin HCl Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Synjardy XR 10/1000 Manufacturer: Boehringer Ingelheim Limited Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	Empagliflozin Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. Metformin HCl Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.	
API Lot No.	Empagliflozin	Metformin HCl
	EPG-201901001	MFH-110/18

Description of Pack (Container closure system)	White colored labeled cardboard box contains pink color, oblong biconvex plain on both side film coated tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin Quantity: 2 kg Clearance Date: 07-03-2019 Metformin HCl Quantity: 2000 kg Clearance Date: 04-03-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of both API manufacturers (Empagliflozin & Metformin HCl) issued by regulatory authority of the country and should be in force till date.	Submitted
1.3.4	Please submit section approval letter of Tablet (General) Section approved by Central Licensing Board.	Submitted
3.2.P.5	Please specify the tests performed for solution of coating containing drug substance Empaglifozin.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1551.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Private Limited.** **(DML # 000333)** **14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceuticals Private Limited.** **(DML # 000333)** **14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04-11-2021
	Evidence of approval of manufacturing facility	Central Licensing Board in its 272nd meeting held on 17th October 2019 approved the renewal of DML including Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13524 dated 31-05-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-04-2023 Slip # 0038467701
	The proposed proprietary name / brand name	Emdagan Plus XR Tablet 12.5/1000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Extended release core tablet of Metformin HCl ……. 1000 mg With coating of immediate release drug substance Empagliflozin ……. 12.5 mg
	Pharmaco-therapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Oral film coated extended release tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR® tablet , USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Erli Plus XR Tablet Manufacturer: PharmEvo
	Name and address of API manufacturer.	<u>Empagliflozin</u> Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. <u>Metformin HCl</u> Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	<u>Empagliflozin</u> Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH <u>Metformin HCl</u> Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Synjardy XR 12.5/1000 Manufacturer: Boehringer Ingelheim Limited Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	<u>Empagliflozin</u> Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. <u>Metformin HCl</u> Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.	
API Lot No.	Empagliflozin	Metformin HCl
	EPG-201901001	MFH-110/18
Description of Pack (Container closure system)	White colored labeled cardboard box contains orange color, oblong biconvex plain on both side film coated tablets.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 06 months	

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin Quantity: 2 kg Clearance Date: 07-03-2019 Metformin HCl Quantity: 2000 kg Clearance Date: 04-03-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of both API manufacturers (Empagliflozin & Metformin HCl) issued by regulatory authority of the country and should be in force till date.	Submitted
1.3.4	Please submit section approval letter of Tablet (General) Section approved by Central Licensing Board.	Submitted
3.2.P.5	Please specify the tests performed for solution of coating containing drug substance Empaglifozin.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1552.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Private Limited. (DML # 000333) 14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	**M/s Shaigan Pharmaceuticals Private Limited. (DML # 000333) 14-km Adyala Road, Post Office Dahgal, Rawalpindi.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04-11-2021
	Evidence of approval of manufacturing facility	Central Licensing Board in its 272nd meeting held on 17th October 2019 approved the renewal of DML including Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13525 dated 31-05-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-04-2023 Slip # 652658660650
	The proposed proprietary name / brand name	Emdagan Plus XR Tablet 25/1000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Extended release core tablet of Metformin HCl ……. 1000 mg With coating of immediate release drug substance Empagliflozin ……. 25 mg
	Pharmaco-therapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Oral film coated extended release tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR® tablet , USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Erli Plus XR Tablet Manufacturer: PharmEvo
	Name and address of API manufacturer.	<u>Empagliflozin</u> Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. <u>Metformin HCl</u> Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH Metformin HCl Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Synjardy XR 25/1000 Manufacturer: Boehringer Ingelheim Limited Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin Name: M/s Jiangsu Yongan Pharmaceutical. Address: No. 18, 237 provincial Road, Economic Development Zone, Huaian, Jiangsu China. Metformin HCl Name: M/s Smruthi Organics Limited Address: A-27, M.I.D.C. Chincholi, Tal-Mohol Solapur, Maharashtra India.		
API Lot No.	Empagliflozin	Metformin HCl	
	EPG-201901001	MFH-110/18	
Description of Pack (Container closure system)	White colored labeled cardboard box contains brown color, oblong biconvex plain on both side film coated tablets.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2020	02-2020	02-2020

Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin Quantity: 2 kg Clearance Date: 07-03-2019 Metformin HCl Quantity: 2000 kg Clearance Date: 04-03-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of both API manufacturers (Empagliflozin & Metformin HCl) issued by regulatory authority of the country and should be in force till date.	Submitted
1.3.4	Please submit section approval letter of Tablet (General) Section approved by Central Licensing Board.	Submitted
3.2.P.5	Please specify the tests performed for solution of coating containing drug substance Empaglifozin.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 02nd June 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Vision Pharmaceuticals (Pvt.) Ltd (DML # 000517) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad**, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2021-2022** and requested for priority consideration of following molecule.

1553.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (Pvt.) Ltd. (DML # 000517) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Vision Pharmaceuticals (Pvt.) Ltd. (DML # 000517) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate valid up to 12-01-2025
	Evidence of approval of manufacturing facility	Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29733 dated 19-10-2022
	Details of fee submitted	PKR 75,000/-: Dated 14-10-2022 Slip # 798396437
	The proposed proprietary name / brand name	Fentrex Tablet 150/500
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Ibuprofen …… 150 mg Paracetamol …… 500 mg
	Pharmaco-therapeutic Group of (API)	Combination of Antipyretic & NSAID
	Pharmaceutical form of applied drug	Oral film coated Tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Brand Name: Provas Duo Manufacturer: Sami Pharma Reg. # 108837
	Name and address of API manufacturer.	<u>Ibuprofen</u> Name: M/s Hubei Granules-Biocause Pharmaceutical Co. Ltd. Address: 122 Yangwan Road, Jingmen City, Hubei Province, People's Republic of China. GMP validity: 29-10-2025 <u>Paracetamol</u> Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Ibuprofen Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH Paracetamol Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 72 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Combogesic Manufacturer: Thornton & Ross Ltd, Linthwaite, Huddersfield, HD7 5QH, UK Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Ibuprofen Name: M/s Hubei Granules-Biocause Pharmaceutical Co. Ltd. Address: 122 Yangwan Road, Jingmen City, Hubei Province, People's Republic of China. Paracetamol Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	Ibuprofen	Paracetamol	
	C100-1904272M	00510911/018/2018	
Description of Pack (Container closure system)	Off white color tablets blistered in ALU-ALU foil packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	NPD 915 T-01	NPD 915 T-03	NPD 915 T-02
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	09-2019	09-2019	09-2019

Date of Initiation	12-10-2019	12-10-2019	12-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ibuprofen Quantity: 25 kg Clearance Date: 19-07-2019 Paracetamol Local procurement from API manufacturer approved by Licensing Division, DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of firm
1.6.5	Please submit GMP certificate of API manufacturer (Ibuprofen) issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.5	For dissolution profile of drug product, please provide the reference. Please justify the speed RPM 75 for selection of sampling time at 15 minutes, 40 minutes & 60 minutes.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 20th July 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Vision Pharmaceuticals (Pvt.) Ltd (DML # 000517) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad**, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2022-2023** and requested for priority consideration of following molecule.

1554.	**Contract Manufacturing**	
	Contract Giver **Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (Pvt.) Ltd. (DML # 000517) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Global Pharmaceuticals Pvt. Ltd (DML # 000417) Plot No. 204-205 Industrial Triangle Kahuta Road Islamabad.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11133 (dated: 04-05-2023)
	Details of fee submitted	PKR 75,000/-: dated: 13-04-2023 (Invoice # 1082201384)
	The proposed proprietary name / brand name	TAM-V Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard Gelatin capsule contains: Soft gelatin capsule of Dutasteride ..…… 0.5 mg Tamsulosin HCl (as modified release pellets 0.2%) …0.4mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules
	Pharmacotherapeutic Group of (API)	Type I and II 5 Alpha-reductase Inhibitor and Alpha1-adrenoreceptor Antagonist
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10s & 20s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Health Canada Approved formulation
	For generic drugs (me-too status)	Duodart Capsule by GSK
	Section Approval Letter from Licensing Division of DRAP	GMP compliant status in last renewal of DML of the firm.
	GMP status of the Finished product manufacturer	GMP certificate issued on the basis of inspection report dated 03-01-2022.
	Name and address of API manufacturer.	<u>Dutasteride</u> Name: M/s Stermone Chemicals (Pvt.) Ltd Address: Survey # 36, Golana Road, Paldi – 288 620, Sokhada, Tal-Khambhat, Dist. Anand, Gujarat, India. GMP Validity: 13-06-2024 <u>Soft Gel of Dutasteride *(Intermediate)*</u> M/s Global Pharmaceuticals Pvt. Ltd (DML # 000417) Plot No. 204-205 Industrial Triangle Kahuta Road Islamabad. <u>Pellets of Tamsulosin HCl *(Intermediate)*</u> Name: M/s Vision Pharmaceuticals (DML # 806) Address: Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Pellets of Tamsulosin HCl Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Dutasteride Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Name: Duodart Capsules Manufacturer: M/s GSK Testing parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	Dutasteride Name: M/s Stermone Chemicals (Pvt.) Ltd Address: Survey # 36, Golana Road, Paldi – 288 620, Sokhada, Tal-Khambhat, Dist. Anand, Gujarat, India. Soft Gel of Dutasteride *(Intermediate)* M/s Global Pharmaceuticals Pvt. Ltd (DML # 000417) Plot No. 204-205 Industrial Triangle Kahuta Road Islamabad. Pellets of Tamsulosin HCl *(Intermediate)* Name: M/s Vision Pharmaceuticals (DML # 806) Address: Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	Dutasteride	Pellets of Tamsulosin HCl	
	2105R0004	2111R0066	
Description of Pack (Container closure system)	Off white spherical pellets filled in empty HGSC with off white soft gel capsule containing clear colourless translucent oily solution.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	22C135	22C136	22C135
Batch Size	200,000 Capsules	200,000 Capsules	200,000 Capsules
Manufacturing Date	03-2022	03-2022	03-2022

Date of Initiation	06-03-2022	18-03-2022	06-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Dutasteride Quantity: 01 kg Clearance date: 26-04-2021 Pellets of Tamsulosin HCl Quantity: 500 kg Clearance date: locally purchases
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1555. Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 2nd June 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Searle Pakistan Limited. (DML # 000012)**, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2020-2021** and requested for priority consideration of following molecule.

Name, address of Applicant / Marketing Authorization Holder	**M/s Searle Pakistan Limited. (DML # 000012)** ***(Formerly M/s OBS Pakistan (Pvt.) Ltd)*** **Plot # C-14, Manghopir Road, S.I.T.E. Karachi.**
Name, address of Manufacturing site.	**M/s Searle Pakistan Limited. (DML # 000012)** ***(Formerly M/s OBS Pakistan (Pvt.) Ltd)*** **Plot # C-14, Manghopir Road, S.I.T.E. Karachi.**
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	GMP certificate issued on the basis of inspection report dated 08th October 2021
Evidence of approval of manufacturing facility	Central Licensing Board in its 277th meeting held on 15th & 16th October 2020 approved the renewal of DML including Tablet (General) Section.
Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13183 dated 29-05-2023
	Details of fee submitted	PKR 30,000/-: Dated 19-04-2023 Slip # 5016355952
	The proposed proprietary name / brand name	Maltofer Chewable Tablet 100 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable Tablet Contains: Iron (III) Hydroxide polymaltose complex equivalent to Iron (III) …… 100 mg
	Pharmaco-therapeutic Group of (API)	Oral Iron Preparation
	Pharmaceutical form of applied drug	Oral chewable Tablet
	Reference to Finished product specifications	Vifor's Specifications
	Proposed Pack size	20s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maltofer by Vifor Switzerland
	For generic drugs (me-too status)	Brand Name: Rubifer Tablets 100 mg Manufacturer: AGP
	Name and address of API manufacturer.	Name: Vifor (International) Inc. Address: Rechenstrasse 37, 9014 St. Gallen Switzerland. GMP validity: 10-11-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Rubifer 100 mg Manufacturer: AGP Pakistan Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Vifor (International) Inc. Address: Rechenstrasse 37, 9014 St. Gallen Switzerland.		
API Lot No.	989201M		
Description of Pack (Container closure system)	ALU-ALU Blister further packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	059DT02	059DT03	059DT02
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-07-2021	15-07-2021	15-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 1.953.6 kg Clearance Date: 09-09-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted

3.2.P.2	Please justify that why Sodium Cyclamate in the formulation of reference product has been replaced with aspartame in your drug product? Please justify the addition of two additional excipients (Povidone K-30 & isopropyl alcohol)	Sodium cyclamate banned in Pakistan. Aspartame has been used at place of sodium cyclamate.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 2nd June 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Searle Pakistan Limited. (DML # 000012)**, has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2020-2021** and requested for priority consideration of following molecule.

1556.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. (DML # 000503)**
	Name, address of Manufacturing site.	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. (DML # 000503)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 15th February 2023.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 175th meeting granted Tablet (General) Section to the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 15115 dated 15-06-2023
	Details of fee submitted	PKR 30,000/-: Dated 24-03-2022 Slip # 0016481547
	The proposed proprietary name / brand name	Tablet Vorix 20 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vortioxetine Hydrobromide equivalent to Vortioxetine …… 20 mg
	Pharmaco-therapeutic Group of (API)	Antidepressants Serotonin Modulators.
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved BRINTELLIX (vortioxetine) tablets

	For generic drugs (me-too status)	Brand Name: Wertioxine 20mg Tablet Manufacturer: Werrick Pharmaceuticals
	Name and address of API manufacturer.	Name: Liyanguang Jari Pharmaceutical Co. Ltd. Address: No. 18, Zhenhua Road, Lianyungang, China. GMP validity: 11-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Brintellix 20 mg Manufacturer: Lundbeck Denmark Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Liyanguang Jari Pharmaceutical Co. Ltd. Address: No. 18, Zhenhua Road, Lianyungang, China.
API Lot No.	20201203
Description of Pack (Container closure system)	ALU-ALU Blister of 10's packed in printed unit carton, further packed in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	0.4 kg	0.4 kg	0.4 kg
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	06-10-2021	06-10-2021	06-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
3.2.S.5	Drug substance manufacturer as well as drug product manufacturer are required to submit analytical testing method to confirm the beta (β) polymorph of vortioxetine hydrobromide (HBr).	Submitted
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D used for manufacturing of 0.4kg batch size. Please submit chromatograms and relevant data for content uniformity test.	Submitted
	Please submit the documents for evidence of quantity of API imported.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1557.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. (DML # 000503)**
	Name, address of Manufacturing site.	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. (DML # 000503)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 15th February 2023.

	Evidence of approval of manufacturing facility	Central Licensing Board in its 175th meeting granted Tablet (General) Section to the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17460 dated 12-07-2023
	Details of fee submitted	PKR 30,000/-: Dated 04-07-2023 Slip # 1917897773
	The proposed proprietary name / brand name	Tablet Vorix 10 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vortioxetine Hydrobromide equivalent to Vortioxetine …… 10 mg
	Pharmaco-therapeutic Group of (API)	Antidepressants Serotonin Modulators.
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved BRINTELLIX (vortioxetine) tablets
	For generic drugs (me-too status)	Brand Name: Wertioxine 10mg Tablet Manufacturer: Werrick Pharmaceuticals
	Name and address of API manufacturer.	Name: Liyanguang Jari Pharmaceutical Co. Ltd. Address: No. 18, Zhenhua Road, Lianyungang, China. GMP validity: 11-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Brintellix 20 mg Manufacturer: Lundbeck Denmark Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: Liyanguang Jari Pharmaceutical Co. Ltd. Address: No. 18, Zhenhua Road, Lianyungang, China.		
API Lot No.	20201203		
Description of Pack (Container closure system)	ALU-ALU Blister of 10's packed in printed unit carton, further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	0.4 kg	0.4 kg	0.4 kg
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	06-10-2021	06-10-2021	06-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity

		monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
3.2.S.5	Drug substance manufacturer as well as drug product manufacturer are required to submit analytical testing method to confirm the beta (β) polymorph of vortioxetine hydrobromide (HBr).	Submitted
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D used for manufacturing of 0.4kg batch size. Please submit chromatograms and relevant data for content uniformity test. Please submit the documents for evidence of quantity of API imported.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 22nd January 2024 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795)**, has achieved the benchmark of more than 100,000 USD worth of export of medicines during the fiscal year 2022-2023 and requested for priority consideration of following molecules.

1558.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04th July 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 274th meeting held on 07th April 2020 approved the amendments/revision in manufacturing facility of firm including Tablet (General Section.)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14524 dated 09-06-2023
	Details of fee submitted	PKR 30,000/-: Dated 02-06-2023 Slip # 281163324699
	The proposed proprietary name / brand name	Tablet Stark 150 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibandronate monosodium monohydrate 168.75mg equivalent to ibandronic acid …… 150 mg
	Pharmaco-therapeutic Group of (API)	Inhibitor of osteoclast-mediated bone resorption
	Pharmaceutical form of applied drug	Film coated tablet

	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved BONVIVA tablets
	For generic drugs (me-too status)	Brand Name: Bonviva Tablet 150 mg Manufacturer: Martin Dow
	Name and address of API manufacturer.	Ibandronate Sodium Monohydrate (Polymorph-B) Name: Fleming Laboratories Limited Address: Plot # 152 & 160, Phase-V, IDA, Jeedimetla (V), Quthbullpur (M), Medchal – Malkajigiri District, Telangana State, India. GMP validity: 31-12-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Bonviva 150 mg Manufacturer: Martin Dow Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	Name: Fleming Laboratories Limited	

	Address: Plot # 152 & 160, Phase-V, IDA, Jeedimetla (V), Quthbullpur (M), Medchal – Malkajigiri District, Telangana State, India.		
API Lot No.	IBB/01211002		
Description of Pack (Container closure system)	ALU-ALU Blister of 10's packed in printed unit carton, further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	STK(150)-ST-001	STK(150)-ST-002	STK(150)-ST-003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	05-11-2022	05-11-2022	05-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 1.5 kg Clearance Date: 05-07-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit evidence of approval of manufacturing facility of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2.S.4	As per the claim of drug substance manufacturer, please submit documents / information for confirmation that there is no Polymorph A but only Polymorph-B of drug substance Ibandronate Sodium is present.	We do hereby confirm that polymorph A is not present and for this the manufacturer has also conducted different testing i.e. IR, X-Ray diffraction, Differential scanning calorimetry, thermo Gravimetrical analysis on their experimental batches. Evidences of Chromatograms were also attached in already submitted dossier in Module 3 Section 3.2.S.3.1.2, Page No: 26 to Page No: 44.

3.2.S.7	Please submit stability data of drug substance according to the climatic condition of Pakistan (Zone-IV).	Submitted
3.2.P.2	Please justify the slower release profile of your drug product than Dissolution profiles of the Bondronat® and Bonviva® tablets avaialble in the public assessment report of EMA wherein release media and at different pH, the innovator / reference products were proved to be pH independent and all samples dissolved faster that 85% in 15 minutes in all pH's.	In pH 1.2, more than 85% of the labeled amount of Ibandronic acid was released in 15 minutes both for sample product and innovator product. The dissolution test in pH 1.2 simulates the acidic environment of the stomach, where Ibandronic acid is highly soluble and rapidly dissolves. In pH 4.5 and 6.8, the dissolution profile of the test product is similar to that of the reference product (Bonviva 150 mg tablets) using the similarity factor (f2). The dissolution test in pH 4.5 and 6.8 simulates the alkaline environment of the lower part of the small intestine and the colon, where Ibandronic acid is poorly soluble and slowly dissolves. The dissolution similarity between the test and reference products ensures that the drug release and bioavailability are comparable and consistent in these regions
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D used for manufacturing of batch size of 1000 tablets.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1559.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04th July 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 274th meeting held on 07th April 2020 approved the amendments/revision in manufacturing facility of firm including Tablet (General Section.)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 9095 dated 04-04-2023
	Details of fee submitted	PKR 30,000/-: Dated 22-3-2023 Slip # 6937235118

	The proposed proprietary name / brand name	Tablet Volvo 5/80 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to amlodipine …… 5 mg Valsartan …..…… 80 mg
	Pharmaco-therapeutic Group of (API)	Calcium Channel Blocker + ARB
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 14
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Exforge Tablet 5/80
	For generic drugs (me-too status)	Brand Name: Amstan Tablet 5/80 mg Manufacturer: Getz
	Name and address of API manufacturer.	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. GMP validity: 31-12-2027 Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China. GMP validity: 28-01-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amlodipine Besylate Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH Valsartan Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Exforge 5/80 Manufacturer: Novartis Testing Parameters: USP Specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China.		
API Lot No.	Valsartan	Amlodipine Besylate	
	10252-210205	21ADL006	
Description of Pack (Container closure system)	ALU-ALU Blister of 2 x 7s packed in packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	VOL(5/80)-ST-001	VOL(5/80)-ST-002	VOL(5/80)-ST-003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-08-2022	27-08-2022	27-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Valsartan Quantity: 12 kg Clearance Date: 21-06-2021 Amlodipine Besylate

		Quantity: 0.7 kg Clearance Date: 21-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	In the Batch analysis report of Herbion, please justify that why assay limits of amlodipine Besylate has been mentioned as 98% - 102% while USP specification limits are 97% -102%?	Please accept our sincerest apologies for any confusion or inconvenience this may have caused. Rest assured, we have rectified the issue and prepared an updated batch analysis report with the correct assay limits, aligning them with the USP monograph standards.
	Please justify that why the value of results of absorbance of valsartan in drug manufacturer batch analysis report is too far from the absorbance value of valsartan in drug substance manufcaturer's report?	Although our obtained absorbance result of 0.018 falls comfortably within the defined limit in accordance with the specifications outlined in United states Pharmacopeia (USP), where the limit for specific test, Absorbance is Not More Than (NMT) 0.02, and the difference in absorbance results from manufacturer is may be due to difference in handling, equipment and lab to lab variation but it is not having impact on our product quality.
3.2.S.7	Please submit stability data of drug substance (Amlodipine Besylate) according to the climatic condition of Pakistan (Zone-IV).	Submitted
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D used for manufacturing of batch size of 1000 tablets. Please submit COAs of APIs used in manufacturing of stability batches. Please submit DRAP clearance documents & evidence of quantity of APIs imported. Please submit stability data of three batches for the last interval (6^{th} month) both for accelerated and long term conditions.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1560.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04th July 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 274th meeting held on 07th April 2020 approved the amendments/revision in manufacturing facility of firm including Tablet (General Section.)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 9096 dated 04-04-2023
	Details of fee submitted	PKR 30,000/-: Dated 22-3-2023 Slip # 3208498052
	The proposed proprietary name / brand name	Tablet Volvo 5/160 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to amlodipine …… 5 mg Valsartan …..…… 160 mg
	Pharmaco-therapeutic Group of (API)	Calcium Channel Blocker + ARB
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 14
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Exforge Tablet 5/160
	For generic drugs (me-too status)	Brand Name: Amstan Tablet 5/160 mg Manufacturer: Getz
	Name and address of API manufacturer.	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. GMP validity: 31-12-2027 Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China. GMP validity: 28-01-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amlodipine Besylate Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH Valsartan Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Exforge 5/160 Manufacturer: Novartis Testing Parameters: USP Specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China.	
API Lot No.	Valsartan	Amlodipine Besylate
	10252-210205	21ADL006
Description of Pack (Container closure system)	ALU-ALU Blister of 2 x 7s packed in packed in unit carton.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 06 months	

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	VOL(5/160)-ST-001	VOL(5/160)-ST-002	VOL(5/160)-ST-003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-08-2022	27-08-2022	27-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Valsartan Quantity: 12 kg Clearance Date: 21-06-2021 Amlodipine Besylate Quantity: 0.7 kg Clearance Date: 21-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	In the Batch analysis report of Herbion, please justify that why assay limits of amlodipine Besylate has been mentioned as 98% - 102% while USP specification limits are 97% -102%?	Please accept our sincerest apologies for any confusion or inconvenience this may have caused. Rest assured, we have rectified the issue and prepared an updated batch analysis report with the correct assay limits, aligning them with the USP monograph standards.
	Please justify that why the value of results of absorbance of valsartan in drug manufacturer batch analysis report is too far from the absorbance value of valsartan in drug substance manufcaturer's report?	Although our obtained absorbance result of 0.018 falls comfortably within the defined limit in accordance with the specifications outlined in United states Pharmacopeia (USP), where the limit for specific test, Absorbance is Not More Than (NMT) 0.02, and the difference in absorbance results from manufacturer is may be due to difference in handling, equipment and lab to lab variation but it is not having impact on our product quality.
3.2.S.7	Please submit stability data of drug substance (Amlodipine Besylate) according to the climatic condition of Pakistan (Zone-IV).	Submitted
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D	Submitted

	used for manufacturing of batch size of 1000 tablets. Please submit COAs of APIs used in manufacturing of stability batches. Please submit DRAP clearance documents & evidence of quantity of APIs imported. Please submit stability data of three batches for the last interval (6th month) both for accelerated and long term conditions.	

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1561.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Herbion Pakistan (Pvt) Ltd. (DML # 000795) Industrial Triangle Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 04th July 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 274th meeting held on 07th April 2020 approved the amendments/revision in manufacturing facility of firm including Tablet (General Section.)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8951 dated 03-04-2023
	Details of fee submitted	PKR 30,000/-: Dated 22-03-2023 Slip # 075755551079
	The proposed proprietary name / brand name	Tablet Volvo 10 /160 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine besylate equivalent to amlodipine …… 10 mg Valsartan …..…… 160 mg
	Pharmaco-therapeutic Group of (API)	Calcium Channel Blocker + ARB
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 14
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Exforge Tablet 10/160

	For generic drugs (me-too status)	Brand Name: Amstan Tablet 10/160 mg Manufacturer: Getz
	Name and address of API manufacturer.	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. GMP validity: 31-12-2027 Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China. GMP validity: 28-01-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amlodipine Besylate Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH Valsartan Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Tablet Exforge 10/160 Manufacturer: Novartis Testing Parameters: USP Specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Amlodipine Besylate Name: Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar, Gujarat, India. Valsartan Name: Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone,Taizhou City, China.		
API Lot No.	Valsartan	Amlodipine Besylate	
	10252-210205	21ADL006	
Description of Pack (Container closure system)	ALU-ALU Blister of 2 x 7s packed in packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	VOL(10/160)-ST-001	VOL(10/160)-ST-002	VOL(10/160)-ST-003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-08-2022	27-08-2022	27-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Valsartan Quantity: 12 kg Clearance Date: 21-06-2021 Amlodipine Besylate Quantity: 0.7 kg Clearance Date: 21-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	In the Batch analysis report of Herbion, please justify that why assay limits of amlodipine	Please accept our sincerest apologies for any confusion or inconvenience this may have caused. Rest assured, we have rectified the issue

	Besylate has been mentioned as 98% - 102% while USP specification limits are 97% -102%?	and prepared an updated batch analysis report with the correct assay limits, aligning them with the USP monograph standards.
	Please justify that why the value of results of absorbance of valsartan in drug manufacturer batch analysis report is too far from the absorbance value of valsartan in drug substance manufcaturer's report?	Although our obtained absorbance result of 0.018 falls comfortably within the defined limit in accordance with the specifications outlined in United states Pharmacopeia (USP), where the limit for specific test, Absorbance is Not More Than (NMT) 0.02, and the difference in absorbance results from manufacturer is may be due to difference in handling, equipment and lab to lab variation but it is not having impact on our product quality.
3.2.S.7	Please submit stability data of drug substance (Amlodipine Besylate) according to the climatic condition of Pakistan (Zone-IV).	Submitted
3.2.P.8	Please provide the details of relevant manufacturing instrument / equipment of R&D used for manufacturing of batch size of 1000 tablets. Please submit COAs of APIs used in manufacturing of stability batches. Please submit DRAP clearance documents & evidence of quantity of APIs imported. Please submit stability data of three batches for the last interval (6th month) both for accelerated and long term conditions.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 22nd January 2024 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616)**, has achieved the benchmark of more than 100,000 USD worth of export of medicines during the fiscal year 2022-2023 and requested for priority consideration of following molecules.

1562.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**
	Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 03rd January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 214th meeting held on 08th October 2008 approved the Grant of additional sections including Liquid Vial Injection (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14713 dated 12-06-2023
	Details of fee submitted	PKR 30,000/-: Dated 01-06-2023 Slip # 596905360
	The proposed proprietary name / brand name	Safari Injection 50mg/ml (2ml glass vial)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Ferric carboxymaltose equivalent to Iron …… 100 mg
	Pharmaco-therapeutic Group of (API)	For the treatment of Iron deficiency
	Pharmaceutical form of applied drug	Sterile Solution for IV injection/infusion
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	2 ml glass vial (1's, 5's,10's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Brand Name: Ferinject injection Manufacturer: OBS
	Name and address of API manufacturer.	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China. GMP validity: 08-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: FCM Injection Manufacturer: Genix Pharma Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China.
API Lot No.	FCM-211204
Description of Pack (Container closure system)	2ml clear glass vials covered with rubber stopper and sealed with flip off seal.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	T-002	T-003	T-004
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	07-10-2022	07-10-2022	07-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 10 kg Clearance Date: 18-04-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	Please submit documented evidence for determination of iron colloid characteristics.	Firm submitted COA mentioning test for Molecular weight determination for which analytical method along

		with proof of availability of required equipment submitted.
	Please submit quantity of water in API.	Firm needs to submit analytical method long with proof of required equipment / instrument.
3.2.S.7	Please justify your stability studies data of ferric carboxymaltose conducted at long term conditions (25^{O}C/RH 60%) while the storage condition mentioned on material safety data sheet is (2-8°C)?	Submitted
	Please submit stability data of drug substance according to the climatic condition of Pakistan (Zone-IV).	Firm again submitted stability data for long term conditions at 30^{O}C / RH 65% while the MSDS requires refrigeration temperature 2^{O}C -8^{O}C.
3.2.P.3	Please justify for not including steam sterilization / terminal sterilization after filling of drug product in vials while it is a critical process parameter in the manufacturing of innovator product.	Submitted
3.2.P.5	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate matter, pH, degradation products, osmolality, density, iron(II) content, free iron content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	Firm submitted the COA of drug product containing information of all the result.
3.2.P.8	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate matter, pH, degradation products, osmolality, density, iron(II) content, free iron content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	Firm submitted the COA of drug product containing information of all the results.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1563.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**

	Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 03rd January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 214th meeting held on 08th October 2008 approved the Grant of additional sections including Liquid Vial Injection (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 15383 dated 19-06-2023
	Details of fee submitted	PKR 30,000/-: Dated 01-06-2023 Slip # 60427952792
	The proposed proprietary name / brand name	Safari Injection 50mg/ml (10ml glass vial)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml contains: Ferric carboxymaltose equivalent to Iron …… 500 mg
	Pharmaco-therapeutic Group of (API)	For the treatment of Iron deficiency
	Pharmaceutical form of applied drug	Sterile Solution for IV injection/infusion
	Reference to Finished product specifications	Manufacture's Specifications
	Proposed Pack size	10 ml glass vial (1's, 5's,10's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Brand Name: Ferinject injection Manufacturer: OBS
	Name and address of API manufacturer.	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China. GMP validity: 08-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical

		form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: FCM Injection Manufacturer: Genix Pharma Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China.		
API Lot No.	FCM-211204		
Description of Pack (Container closure system)	10ml clear glass vials covered with rubber stopper and sealed with flip off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-004
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	29-09-2022	29-09-2022	29-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 10 kg Clearance Date: 18-04-2022

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	Please submit documented evidence for determination of iron colloid characteristics.	Firm submitted COA mentioning test for Molecular weight determination for which analytical method along with proof of availability of required equipment submitted.
	Please submit quantity of water in API.	Firm needs to submit analytical method long with proof of required equipment / instrument.
3.2.S.7	Please justify your stability studies data of ferric carboxymaltose conducted at long term conditions ($25^{O}C$/RH 60%) while the storage condition mentioned on material safety data sheet is (2-8°C)?	Submitted
	Please submit stability data of drug substance according to the climatic condition of Pakistan (Zone-IV).	Firm again submitted stability data for long term conditions at $30^{O}C$ / RH 65% while the MSDS requires refrigeration temperature $2^{O}C$ -$8^{O}C$.
3.2.P.3	Please justify for not including steam sterilization / terminal sterilization after filling of drug product in vials while it is a critical process parameter in the manufacturing of innovator product.	Submitted
3.2.P.5	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate matter, pH, degradation products, osmolality, density, iron(II) content, free iron content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	Firm submitted the COA of drug product containing information of all the result.
3.2.P.8	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate	Firm submitted the COA of drug product containing information of all the results.

	matter, pH, degradation products, osmolality, density, iron(II) content, free iron content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	

Decision: approved with innovator specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1564.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**
	Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 03rd January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 214th meeting held on 08th October 2008 approved the Grant of additional sections including Liquid Vial Injection (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 15384 dated 19-06-2023
	Details of fee submitted	PKR 30,000/-: Dated 01-06-2023 Slip # 580255923259
	The proposed proprietary name / brand name	Safari Injection 50mg/ml (20ml glass vial)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 20 ml contains: Ferric carboxymaltose equivalent to Iron …… 1000 mg (50mg/ml)
	Pharmaco-therapeutic Group of (API)	For the treatment of Iron deficiency
	Pharmaceutical form of applied drug	Sterile Solution for IV injection/infusion
	Reference to Finished product specifications	Manufacture's Specifications
	Proposed Pack size	20 ml glass vial (1's, 5's,10's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Brand Name: Ferinject injection

		Manufacturer: OBS
	Name and address of API manufacturer.	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China. GMP validity: 08-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: FCM Injection Manufacturer: Genix Pharma Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Chongqing Carelife Pharmaceutical Co. Ltd. Address: No. 02, The Third Branch Road, Huanan Road, Yanjia, Changshou, District Changqing, China.		
API Lot No.	FCM-211204		
Description of Pack (Container closure system)	20ml clear glass vials covered with rubber stopper and sealed with flip off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	250 vials	250 vials	250 vials

Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	26-09-2022	26-09-2022	26-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 10 kg Clearance Date: 18-04-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	Please submit documented evidence for determination of iron colloid characteristics.	Firm submitted COA mentioning test for Molecular weight determination for which analytical method along with proof of availability of required equipment submitted.
	Please submit quantity of water in API.	Firm needs to submit analytical method long with proof of required equipment / instrument.
3.2.S.7	Please justify your stability studies data of ferric carboxymaltose conducted at long term conditions (25^{O}C/RH 60%) while the storage condition mentioned on material safety data sheet is (2-8°C)?	Submitted
	Please submit stability data of drug substance according to the climatic condition of Pakistan (Zone-IV).	Firm again submitted stability data for long term conditions at 30^{O}C / RH 65% while the MSDS requires refrigeration temperature 2^{O}C -8^{O}C.
3.2.P.3	Please justify for not including steam sterilization / terminal sterilization after filling of drug product in vials while it is a critical process parameter in the manufacturing of innovator product.	Submitted
3.2.P.5	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate matter, pH, degradation products, osmolality, density, iron(II) content, free iron	Firm submitted the COA of drug product containing information of all the result.

	content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	
3.2.P.8	Please submit report along with raw data / documents for all the quality control tests as per innovator specification (colour of content, appearance of content, identification (by infrared, by X-ray powder diffraction), total iron content, total and unbound carboxymaltose content, average molecular mass, particle size, foreign visible particles, particulate matter, pH, degradation products, osmolality, density, iron(II) content, free iron content, uniformity of dosage units, extractable volume, bacterial endotoxins, sterility, relative labile iron content and iron reduction kinetics.)	Firm submitted the COA of drug product containing information of all the results.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 22nd January 2024 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Hilton Pharma (Pvt) Ltd. (DML # 000136)**, has achieved the benchmark of more than 100,000 USD worth of export of medicines during the fiscal year 2021-2022 and requested for priority consideration of following molecules.

1565.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 23rd January 2023.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 238th meeting held on 19th November 2014 approved the regularization of existing facility of the firm including Injection Vials & Ampoules (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23746 dated 26-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 06-09-2023 Slip # 66156081317

	The proposed proprietary name / brand name	BRIVACE Injection 10mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Brivaracetam …… 50 mg (10mg/ml)
	Pharmaco-therapeutic Group of (API)	Antiepileptics
	Pharmaceutical form of applied drug	Sterile Solution for injection/infusion
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	5 ml Type I glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved Briviact®
	For generic drugs (me-too status)	Brand Name: Cubriva injection Manufacturer: Genix Pharma
	Name and address of API manufacturer.	Name: Chengda Pharmaceuticals Co. Ltd. Address: No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Jiaxing, China. GMP validity: 07-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Briviact Injection 10mg/ml Manufacturer: UCB Group of Companies Testing Parameters: Innovator Specifications

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Chengda Pharmaceuticals Co. Ltd. Address: No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Jiaxing, China.		
API Lot No.	NP1713-2104001		
Description of Pack (Container closure system)	USP Type-I, 5ml, Glass vials.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	BRI-248-2/21	BRI-251-3/21	BRI-252-4/21
Batch Size	7 Litre	7 Litre	7 Litre
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 0.5 kg Clearance Date: 02-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit list of APIs manufactured by drug substance manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved wth innovator specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1566.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136)** **Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136)** **Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 23rd January 2023.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 238th meeting held on 19th November 2014 approved the regularization of existing facility of the firm including Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25888 dated 26-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 13-09-2023 Slip # 0044023539
	The proposed proprietary name / brand name	BRIVACE Oral Solution 10mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Brivaracetam …… 10 mg
	Pharmaco-therapeutic Group of (API)	Antiepileptics
	Pharmaceutical form of applied drug	Sterile Solution for injection/infusion
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	USP type III amber glass bottle (30ml, 60ml, 100ml & 120 ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved Briviact®
	For generic drugs (me-too status)	Brand Name: Cubriva Oral Solution Manufacturer: Genix Pharma
	Name and address of API manufacturer.	Name: Chengda Pharmaceuticals Co. Ltd. Address: No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Jiaxing, China. GMP validity: 07-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Briviact Oral Solution Manufacturer: UCB Group of Companies Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: Chengda Pharmaceuticals Co. Ltd. Address: No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Jiaxing, China.		
API Lot No.	BVT-202104001		
Description of Pack (Container closure system)	USP Type-III, Amber glass bottle.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	BRI-225-05/21	BRI-226-05/21	BRI-227-05/21
Batch Size	5 Litre	5 Litre	5 Litre
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 0.5 kg Clearance Date: 02-09-2021

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit list of APIs manufactured by drug substance manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: approved wth innovator specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1567.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 23rd January 2023.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 238th meeting held on 19th November 2014 approved the regularization of existing facility of the firm including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27434 dated 22-11-2023
	Details of fee submitted	PKR 75,000/-: Dated 20-10-2023 Slip # 365591933632
	The proposed proprietary name / brand name	Fenohil Tablet 10 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 10 mg
	Pharmaco-therapeutic Group of (API)	a nonsteroidal mineralocorticoid receptor antagonist (Diuretics)

	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10s, 14s,20s,28s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved KERENDIA®
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 01, Yunan Street, Kaifeng, Henan Province, China. GMP validity: 07-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Kerendia Tablet 10 mg Manufacturer: Bayer HealthCare Pharmaceuticals Inc. Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 01, Yunan Street, Kaifeng, Henan Province, China.
API Lot No.	HF220525
Description of Pack (Container closure system)	USP Type-III, Amber glass bottle.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	FER-477-05/22	FER-483-06/22	FER-484-07/22
Batch Size	8695 Tablets	8695 Tablets	8695 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	26-01-2023	26-01-2023	26-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit list of APIs manufactured by drug substance manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.S.3	Please submit documented evidence for control on following critical process steps based on their impact on critical quality attributes (CQAs) Enantiomeric separation. Final crystallization. Micronisation of the active substance.	Letter of access (LOA) of API manufacturer submitted.
3.2.S.4	Please justify that why water content test has not been made part of your specifications while it is a critical process parameter in drug substance profile of innovator product?	Loss on Drying (LOD) test is API manufacturer specification and same is followed by Hilton Pharma. LOD covers all type of solvents including water content in the API.
	As per the batch analysis report for API submitted by drug product manufacturer (Hilton), please submit inspection report of your firm mentioning following QC instruments, required for the following tests. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). Malvern master sizer for determination of particle size.	Polymorphic form is Form I. Inspection report of firm submitted.

	Chromatographic column, Chiralpak ID for determination of R-isomer.	
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.	Submitted

Decision: approved wth innovator specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1568.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Hilton Pharma (Pvt) Ltd. (DML # 000136) Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 23rd January 2023.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 238th meeting held on 19th November 2014 approved the regularization of existing facility of the firm including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27435 dated 22-11-2023
	Details of fee submitted	PKR 75,000/-: Dated 20-10-2023 Slip # 9819078368
	The proposed proprietary name / brand name	Fenohil Tablet 20 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 20 mg
	Pharmaco-therapeutic Group of (API)	a nonsteroidal mineralocorticoid receptor antagonist (Diuretics)
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10s, 14s,20s,28s & 30s.
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	MHRA UK approved KERENDIA®
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 01, Yunan Street, Kaifeng, Henan Province, China. GMP validity: 07-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Kerendia Tablet 20 mg Manufacturer: Bayer HealthCare Pharmaceuticals Inc. Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Kaifeng Pharmaceutical (Group) Company Limited. Address: No. 01, Yunan Street, Kaifeng, Henan Province, China.
API Lot No.	HF220525
Description of Pack (Container closure system)	USP Type-III, Amber glass bottle.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	FER-499-08/22	FER-500-09/22	FER-501-07/22
Batch Size	5384 Tablets	5384 Tablets	5384 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	13-12-2022	13-12-2022	13-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: Clearance Date:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit list of APIs manufactured by drug substance manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.S.3	Please submit documented evidence for control on following critical process steps based on their impact on critical quality attributes (CQAs) Enantiomeric separation. Final crystallization. Micronisation of the active substance.	Letter of access (LOA) of API manufacturer submitted.
3.2.S.4	Please justify that why water content test has not been made part of your specifications while it is a critical process parameter in drug substance profile of innovator product?	Loss on Drying (LOD) test is API manufacturer specification and same is followed by Hilton Pharma. LOD covers all type of solvents including water content in the API.
	As per the batch analysis report for API submitted by drug product manufacturer (Hilton), please submit inspection report of your firm mentioning following QC instruments, required for the following tests. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). Malvern master sizer for determination of particle size. Chromatographic column, Chiralpak ID for determination of R-isomer.	Polymorphic form is Form I. Inspection report of firm submitted.
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Please justify that why test of uniformity of dosage form has not been made part of your	Submitted

	stability studies while it is major test for determination of factors impacting CQAs.	

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 22nd January 2024 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Pharmasol (Pvt) Ltd. (DML # 000872)**, has achieved the benchmark of more than 100,000 USD worth of export of medicines during the fiscal year 2021-2022 and requested for priority consideration of following molecules.

1569.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmasol (Pvt) Ltd. (DML # 000872)** **Plot 549, Sunder Industrial estate, Lahore.**
	Name, address of Manufacturing site.	**M/s Pharmasol (Pvt) Ltd. (DML # 000872)** **Plot 549, Sunder Industrial estate, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 22nd August 2022.
	Evidence of approval of manufacturing facility	Submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 19305 dated 03-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 18-07-2023 Slip # 86665132
	The proposed proprietary name / brand name	Polybio Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains sterile powder for injection: Polymyxin B sulfate equivalent to Polymyxin …… 500000 units (50mg/vial)
	Pharmaco-therapeutic Group of (API)	Polypeptide Antibiotics
	Pharmaceutical form of applied drug	Sterile powder for IV Solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's *(10ml USP type I amber tubular glass vial)*
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	N/A

	Name and address of API manufacturer.	Name: North China Pharmaceutical Huasheng Co. Ltd. Address: No. 08, Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei, China. GMP validity: 19-08-2020
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 48 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Viacease B injection Manufacturer: Mylan Testing Parameters: USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: North China Pharmaceutical Huasheng Co. Ltd. Address: No. 08, Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei, China.		
API Lot No.	HON211220IU		
Description of Pack (Container closure system)	USP Type-I, 10ml, amber colored Glass vials.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	E010	E011	E012
Batch Size	125 Vials	125 Vials	125 Vials

Manufacturing Date	11-10-2022	11-10-2022	11-10-2022
Date of Initiation	10-2022	10-2022	10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 40 grams Clearance Date: 30-05-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit list of APIs *(translated in English)* manufactured by drug substance manufacturer issued by regulatory authority of country of origin.	Submitted
	Please submit GMP certificate in English translation which should be readable.	Submitted
3.2.P.5.3	Submit microbial reports for the analytical method verification studies for the drug product.	Submitted
3.2.P.8	Submit stability data of drug product after reconstitution *(in use stability)*	Submitted
	Submit clearance certificate issued by DRAP I&E office confirming the procurement of drug substance.	Submitted
	Justification shall be submitted for not performing test of "Particulate Matter in Injections", "Identification test" and "Residue on ignition test" as recommended by USP monograph, during drug product stability studies.	Submitted
	Complete batch manufacturing record shall be submitted for the trial batches.	Submitted
	Microbiological reports shall be submitted for the Assay analysis performed during stability studies.	Submitted
	Justification of batch size of trial batches shall be submitted against the number of units required for compete stability studies till claimed shelf ife.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 22nd January 2024 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Surge Laboratories (Pvt) Ltd. (DML # 000484),** has achieved the benchmark of more than 100,000 USD worth of export of medicines during the fiscal year 2020-2021 and requested for priority consideration of following molecules.

1570.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories (Pvt) Ltd. (DML # 000484)** **10-Km Faisalabad Road Bhikhi Dist.: Sheikhupura.**
	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate validity (Manufcaturer): 21-05-2025
	Evidence of approval of manufacturing facility	Central Licensing Board in its 273rd meeting held on 15th January 2020 approved the renewal of DML including Capsule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25417 dated 19-10-2023
	Details of fee submitted	PKR 75,000/-: Dated 13-09-2023 Slip # 143120248003
	The proposed proprietary name / brand name	Surlin Capsules 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 50 mg
	Pharmaco-therapeutic Group of (API)	Anti-epileptics
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10s, 14s, 20s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Gabica 50 mg Capsule Manufacturer: Getz Pharma

	Name and address of API manufacturer.	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India. GMP validity: 01-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Gabica Capsule 50 mg Manufacturer: Getz Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India.		
API Lot No.	PG-PI-4000922		
Description of Pack (Container closure system)	Hard gelatin capsule No. 03 with dark purple opaque cap and rich yellow opaque body both imprinted with black color NQ logo containing white to off white colored dry granular powder.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	PDF001	PDE006	
Batch Size	95000 Capsules	150000 Capsules	

Manufacturing Date	02-2023	10-2022	
Date of Initiation	16-02-2023	27-10-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 150 kg Clearance Date: 18-12-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / last renewal letter issued by Secretary, Central Licensing Board, for the manufacturing facility of Capsule (General) Section of the NabiQasim Pharma.	Submitted
	Please submit original contract agreement between the two parties.	Submitted
	Please submit the information/documents related to last inspection of Nabi Qasim Pharma, conducted for the purpose of capacity assessment of Capsule (General) Section.	Inspection for the purpose of capacity assessment of Nabiqasim Industries (Pvt) Ltd. has not been conducted. The firm submitted capacity of manufacturing facility and laboratory.
3.2.P.8	Please submit summary of stability data of three batches of drug product as per format provided in guidelines for submission of FORM 5F-CTD on official website of DRAP and make sure to mention properly, the Batch #, Batch size, Mfg. date, Expiry date, Description of the primary packaging/container, API LOT#, Date of initiation of studies, accelerated or long term conditions etc.	Submitted
	Please submit in tabulated form, the comparison of results of stability data of three batches for all the test mentioned in BP monograph.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1571.	**Contract Manufacturing**

	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories (Pvt) Ltd. (DML # 000484)** **10-Km Faisalabad Road Bhikhi Dist.: Sheikhupura.**
	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105)** **17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate validity: 21-05-2025
	Evidence of approval of manufacturing facility	Central Licensing Board in its 273rd meeting held on 15th January 2020 approved the renewal of DML including Capsule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No GMX-3VR-ETXP dated 30-11-2023
	Details of fee submitted	PKR 75,000/-: Dated 13-09-2023 Slip # 3018763739
	The proposed proprietary name / brand name	Surlin Capsules 25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 25 mg
	Pharmaco-therapeutic Group of (API)	Anti-epileptics
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10s, 14s, 20s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Gabica 25 mg Capsule Manufacturer: Getz Pharma
	Name and address of API manufacturer.	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India. GMP validity: 01-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Gabica Capsule 25 mg Manufacturer: Getz Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India.		
API Lot No.	PG-PI-4000922		
Description of Pack (Container closure system)	Hard gelatin capsule No. 03 with dark purple opaque cap and rich yellow opaque body both imprinted with black color NQ logo containing white to off white colored dry granular powder.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	NO0122		
Batch Size	5000 Capsules	5000 Capsules	
Manufacturing Date	11-2022	11-2022	
Date of Initiation	10-11-2022	10-11-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 150 kg Clearance Date: 18-12-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit the information/documents related to last inspection of Nabi Qasim Pharma, conducted for the purpose of capacity assessment of Capsule (General) Section.	Inspection for the purpose of capacity assessment of Nabiqasim Industries (Pvt) Ltd. has not been conducted.

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1572.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	M/s Surge Laboratories (Pvt) Ltd. (DML # 000484) 10-Km Faisalabad Road Bhikhi Dist.: Sheikhupura.
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 27th May 2022.
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24298 dated 04-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 10-08-2023 Slip # 710405291361
	The proposed proprietary name / brand name	Surlin Capsules 75 mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 75 mg
	Pharmaco-therapeutic Group of (API)	Anti-epileptics
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10s, 14s, 20s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Gabica 75 mg Capsule Manufacturer: Getz Pharma
	Name and address of API manufacturer.	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India. GMP validity: 01-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Gabica Capsule 75 mg Manufacturer: Getz Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India.		
API Lot No.	PG-PI-4000922		
Description of Pack (Container closure system)	Hard gelatin capsule No. 03 with dark purple opaque cap and rich yellow opaque body both imprinted with black color NQ logo containing white to off white colored dry granular powder.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	PCE007	PCF001	
Batch Size	200,000 Capsules	200,000 Capsules	
Manufacturing Date	12/2022	01/2023	
Date of Initiation	18-01-2023	17-01-2023	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 150 kg Clearance Date: 30-09-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / last renewal letter issued by Secretary, Central Licensing Board, for the manufacturing facility of Capsule (General) Section of the NabiQasim Pharma.	Submitted
	Please submit original contract agreement between the two parties.	Submitted
	Please submit the information/documents related to last inspection of Nabi Qasim Pharma, conducted for the purpose of capacity assessment of Capsule (General) Section.	Inspection for the purpose of capacity assessment of Nabiqasim Industries (Pvt) Ltd. has not been conducted but firm has submitted the capacityof manufacturing and testing on stamp paper.

3.2.P.8	Please submit summary of stability data of three batches of drug product as per format provided in guidelines for submission of FORM 5F-CTD on official website of DRAP and make sure to mention properly, the Batch #, Batch size, Mfg. date, Expiry date, Description of the primary packaging/container, API LOT#, Date of initiation of studies, accelerated or long term conditions etc.	Submitted
	Please submit in tabulated form, the comparison of results of stability data of three batches for all the test mentioned in BP monograph.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1573.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	M/s Surge Laboratories (Pvt) Ltd. (DML # 000484) 10-Km Faisalabad Road Bhikhi Dist.: Sheikhupura.
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 27th May 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 273rd meeting held on 15th January 2020 approved the renewal of DML including Capsule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24298 dated 04-10-2023
	Details of fee submitted	PKR 75,000/-: Dated 10-08-2023 Slip # 710405291361
	The proposed proprietary name / brand name	Surlin Capsules 150 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 150 mg
	Pharmaco-therapeutic Group of (API)	Anti-epileptics
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10s, 14s, 20s & 30s.
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Gabica 150 mg Capsule Manufacturer: Getz Pharma
	Name and address of API manufacturer.	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India. GMP validity: 01-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Gabica Capsule 150 mg Manufacturer: Getz Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India.
API Lot No.	PG-PI-4000922
Description of Pack (Container closure system)	Hard gelatin capsule No. 03 with dark purple opaque cap and rich yellow opaque body both imprinted with black color NQ logo containing white to off white colored dry granular powder.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	PAE002	PAE003	PAF001
Batch Size	50,000 Capsules	50,000 Capsules	50,000 Capsules
Manufacturing Date	07-2022	10-2022	02-2023
Date of Initiation	03-08-2022	30-10-2022	18-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 150 kg Clearance Date: 30-09-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / last renewal letter issued by Secretary, Central Licensing Board, for the manufacturing facility of Capsule (General) Section of the NabiQasim Pharma.	Submitted
	Please submit original contract agreement between the two parties.	Submitted
3.2.P.8	Please submit summary of stability data of three batches of drug product as per format provided in guidelines for submission of FORM 5F-CTD on official website of DRAP and make sure to mention properly, the Batch #, Batch size, Mfg. date, Expiry date, Description of the primary packaging/container, API LOT#, Date of initiation of studies, accelerated or long term conditions etc.	Submitted
	Please submit in tabulated form, the comparison of results of stability data of three batches for all the test mentioned in BP monograph.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1574.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories (Pvt) Ltd. (DML # 000484) 10-Km Faisalabad Road Bhikhi Dist.: Sheikhupura.**

	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report dated 27th May 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 273rd meeting held on 15th January 2020 approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. TA1-HH7-P3TW dated 13-12-2023
	Details of fee submitted	PKR 75,000/-: Dated 07-12-2023 Slip # 4294412231
	The proposed proprietary name / brand name	Tablet Surlin CR 165 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Pregabalin …… 165 mg
	Pharmaco-therapeutic Group of (API)	Anti-epileptics
	Pharmaceutical form of applied drug	Controlled released tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10s, 14s, 20s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India. GMP validity: 01-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Lyrica CR 165 mg Tablet Manufacturer: Pfizer Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: Atlas Life Sciences Private Limited. Address: C-1/360-361, G.I.D.C. Estate, Odhav, Ahmedabad, Gujarat, India.		
API Lot No.	PG-1021119		
Description of Pack (Container closure system)	ALU-ALU Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	573DS01	573DS02	573DS03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	03-01-2022	03-01-2022	03-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quantity: 150 kg Clearance Date: 16-12-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / last renewal letter issued by Secretary, Central Licensing Board, for the manufacturing facility of Capsule (General) Section of the NabiQasim Pharma.	Submitted
	Please submit original contract agreement between the two parties.	Submitted
	Please submit the information/documents related to last inspection of Nabi Qasim Pharma, conducted for the purpose of capacity assessment of Capsule (General) Section.	Inspection for the purpose of capacity assessment of Nabiqasim Industries (Pvt) Ltd. has not been conducted.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 04: Priority Molecules applications as per decision of 257th meeting of Drug Registration Board.

1575.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No G8A-TSX-W88Z dated 28-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 17-11-2022 Slip # 09661966934
	The proposed proprietary name / brand name	ODIROX FILM COATED TABLET 90 mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Deferasirox ……. 90 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	3 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADNU 90 mg Tablet
	For generic drugs (me-too status)	Oleptiss 90 mg Manufactured by: NOVARTIS PHARMA AG/PAKISTAN
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Oleptiss Film Coated Tablet 90mg Manufactured by: NOVARTIS PHARMA Testing Parameters: Innovator Specifications

		Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.			
Description of Pack (Container closure system)	The primary container is Alu Alu Blister and the packed in unit Carton as secondary container. (Packs of 30s' 3x10s')		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 90 – 001	TODI – 90 – 002	TODI – 90 – 003
Batch Size	5000 Units	5000 Units	5000 Units
Manufacturing Date	December -2022	December -2022	December -2022
Date of Initiation	12-08-2022	12-08-2022	12-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 issuance date: 02-07-2021 Quantity: 0.1 kg License No: 00692/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

On initial evaluation, following observations were communicated to the firm.

Section	Observations	Status
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet	Submitted

	(General) Section of your firm by Central Licensing Board.	
3.2.P.5.1	Please provide reference for speed of 50RPM for dissolution test while USFDA dissolution database specify Speed of 75RPM for dissolution test.	It was a typographical mistake. The required RPM for dissolution test is 75 RPM while 50 RPM is for our dispersible tablets whose dossiers are also submitted.
3.2. P.5.4	Please clarify the status of batch analysis report of drug products either film coated or dispersible tablets?	Film coated Rectified & attached
3.2.P.8	Please clarify the reason of negative peak in the chromatograms.	The appearance of negative peak in some of the chromatogarms may be due to presence of air bubbles in the coulmn. However, the validation data of analytical method is an evidence that we have no negative peaks during method validation. We have repeated our SOP to confirm the system before start of analysis for any peaks other than the peaks of interest.
	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Attached as reference
	Please submit chromatograms for dissolution tests and calculation sheets.	Attached

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1576.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. 5E7-D3J-LWBU dated 28-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 17-11-2022 Slip # 09661966934
	The proposed proprietary name / brand name	ODIROX FILM COATED TABLET 180 mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Deferasirox ……. 180 mg
	Pharmaco-therapeutic Group of (API)	iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	3 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADNU 180 mg Tablet
	For generic drugs (me-too status)	Oleptiss 180 mg Manufactured by: NOVARTIS PHARMA AG/PAKISTAN
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Oleptiss Film Coated Tablet 180mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications

		Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	4DFX0040622		
Description of Pack (Container closure system)	The primary container is Alu Alu Blister and the packed in unit Carton as secondary container. (Packs of 30s' 3x10s')		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 180 – 001	TODI – 180 – 002	TODI – 180 – 003
Batch Size	5000 Units	5000 Units	5000 Units
Manufacturing Date	December -2022	December -2022	December -2022
Date of Initiation	08-12-2022	08-12-2022	08-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing	Submitted

	License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	
3.2.P.5.1	Please provide reference for speed of 50RPM for dissolution test while USFDA dissolution database specify Speed of 75RPM for dissolution test.	It was a typographical mistake. The required RPM for dissolution test is 75 RPM while 50 RPM is for our dispersible tablets whose dossiers are also submitted.
3.2. P.5.4	Please clarify the status of batch analysis report of drug products either film coated or dispersible tablets?	Film coated Rectified & attached
3.2.P.8	Please clarify the reason of negative peak in the chromatograms.	The appearance of negative peak in some of the chromatogarms may be due to presence of air bubbles in the coulmn. However, the validation data of analytical method is an evidence that we have no negative peaks during method validation. We have repeated our SOP to confirm the system before start of analysis for any peaks other than the peaks of interest.
	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Attached as reference
	Please submit chromatograms for dissolution tests and calculation sheets.	Attached

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1577.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. GQ2-GDQ-JTXH dated 28-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 17-11-2022 Slip # 09661966934

	The proposed proprietary name / brand name	ODIROX FILM COATED TABLET 360 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Deferasirox ……. 360 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	3 x 10s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADNU 360 mg Tablet
	For generic drugs (me-too status)	Oleptiss 360 mg Manufactured by: NOVARTIS PHARMA AG/PAKISTAN
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Oleptiss Film Coated Tablet 360mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	4DFX0040622		
Description of Pack (Container closure system)	The primary container is Alu Alu Blister and the packed in unit Carton as secondary container. (Packs of 30s' 3x10s')		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 360 – 001	TODI – 360 – 002	TODI – 360 – 003
Batch Size	5000 Units	5000 Units	5000 Units
Manufacturing Date	December -2022	December -2022	December -2022
Date of Initiation	12-08-2022	12-08-2022	12-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

Section	Observations	Status
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2.P.5.1	Please provide reference for speed of 50RPM for dissolution test while USFDA dissolution database specify Speed of 75RPM for dissolution test.	It was a typographical mistake. The required RPM for dissolution test is 75 RPM while 50 RPM is for our dispersible tablets whose dossiers are also submitted.
3.2. P.5.4	Please clarify the status of batch analysis report of drug products either film coated or dispersible tablets?	Film coated Rectified & attached
3.2.P.8	Please clarify the reason of negative peak in the chromatograms.	The appearance of negative peak in some of the chromatogarms may be due to presence of air bubbles in the coulmn. However, the validation data of analytical method is an evidence that we have no negative peaks during method validation. We have repeated our SOP to confirm the system before start of analysis for any peaks other than the peaks of interest.
	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Attached as reference
	Please submit chromatograms for dissolution tests and calculation sheets.	Attached

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1578.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. 27574 dated 24-11-2023

	Details of fee submitted	PKR 30,000/-: Dated 04-10-2023 Slip # 92663019862
	The proposed proprietary name / brand name	ODIROX DISPERSIBLE TABLET 100 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Deferasirox ……. 100 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Dispersible tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s (5 x 6)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO recommended formulation (Essential Medicine List) Medicine Affecting the blood https://list.essentialmeds.org/recommendations/1396
	For generic drugs (me-too status)	Daxirox Tablet 100 mg (Reg # 68112) Manufactured by: CCL Pharma
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications,

		reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Asunra Dispersible Tablet 100 mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	4DFX0040622		
Description of Pack (Container closure system)	The primary container is Alu Alu Blister and the packed in unit Carton as secondary container. (Packs of 30s' 3x10s')		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 100 – 001	TODI – 100 – 002	TODI – 100 – 003
Batch Size	1500 Units	1500 Units	1500 Units
Manufacturing Date	November -2022	November -2022	November -2022
Date of Initiation	10-11-2022	10-11-2022	10-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity

		monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
1.5.9	The reference of approval of the formulation in the reference regulatory authority has not been verified. Therefore, please provide approval status in the reference regulatory authorities of the drug product in same strength and formulation as dispersible tablet containing 100 mg deferasirox.	WHO essential list product.
3.2.P.8	Please submit chromatograms for dissolution tests and calculation sheets.	Submitted

Decision: approved with bp specification.

- **Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1579.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. 27575 dated 24-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 04-10-2023 Slip # 950224525
	The proposed proprietary name / brand name	ODIROX DISPERSIBLE TABLET 400 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Deferasirox ……. 400 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03

	Pharmaceutical form of applied drug	Dispersible tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s (5 x 6)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO recommended formulation (Essential Medicine List) Medicine Affecting the blood https://list.essentialmeds.org/recommendations/1396
	For generic drugs (me-too status)	AsunraTablet 400 mg Manufactured by: Novartis Pharma
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District, Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Asunra Dispersible Tablet 400 mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	4DFX0040622		
Description of Pack (Container closure system)	The primary container is Alu Alu Blister and the packed in unit Carton as secondary container. (Packs of 30s' 3x10s')		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 400 – 001	TODI – 400 – 002	TODI – 400 – 003
Batch Size	1500 Units	1500 Units	1500 Units
Manufacturing Date	November -2022	November -2022	November -2022
Date of Initiation	10-11-2022	10-11-2022	10-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
1.5.9	The reference of approval of the formulation in the reference regulatory authority has not been verified. Therefore, please provide approval status in the reference regulatory authorities of the drug product in same strength and formulation as dispersible tablet containing 400 mg deferasirox.	WHO essential list product.

3.2.P.8	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Submitted
	Please submit chromatograms for dissolution tests and calculation sheets.	Submitted

Decision: approved with bp specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021.

1580.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. GU4-D3V-1QH2 dated 11-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 17-11-2022 Slip # 950224525
	The proposed proprietary name / brand name	ODIROX DISPERSIBLE TABLET 250 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Deferasirox ……. 250 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Dispersible tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s (5 x 6)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADENU 250 mg Tablet

	For generic drugs (me-too status)	AsunraTablet 250 mg Manufactured by: Novartis Pharma
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Asunra Dispersible Tablet 250 mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.
API Lot No.	4DFX0040622
Description of Pack (Container closure system)	A White HDPE bottle with induction seal containing 30s' tablets with printed adhesive label Packs of 30s'
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 250 – 001	TODI – 250 – 002	TODI – 250 – 003
Batch Size	1500 Units	1500 Units	1500 Units
Manufacturing Date	November -2022	November -2022	November -2022
Date of Initiation	10-11-2022	10-11-2022	10-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2.P.5.1	Please provide reference for speed of 50RPM for dissolution test while USFDA dissolution database specify Speed of 75RPM for dissolution test.	It was a typographical mistake. The required RPM for dissolution test is 75 RPM while 50 RPM is for our dispersible tablets whose dossiers are also submitted.
3.2. P.5.4	Please clarify the status of batch analysis report of drug products either film coated or dispersible tablets?	Film coated Rectified & attached

3.2.P.8	Please clarify the reason of negative peak in the chromatograms.	The appearance of negative peak in some of the chromatogarms may be due to presence of air bubbles in the coulmn. However, the validation data of analytical method is an evidence that we have no negative peaks during method validation. We have repeated our SOP to confirm the system before start of analysis for any peaks other than the peaks of interest.
	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Attached as reference
	Please submit chromatograms for dissolution tests and calculation sheets.	Attached

Decision: approved with bp specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021.

1581.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s A.J. MIRZA PHARMA (PVT.) LTD. (DML # 000234) Plot No.44, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 08-11-2022
	Evidence of approval of manufacturing facility	Central Licensing Board in its 288th meeting held on 18th October 2022 has considered and grant the DML including Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No. 7AS-3NE-QMYZ dated 07-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 17-11-2022 Slip # 574867784380
	The proposed proprietary name / brand name	ODIROX DISPERSIBLE TABLET 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Deferasirox ……. 500 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03

	Pharmaceutical form of applied drug	Dispersible tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s (5 x 6)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADENU 500 mg Tablet
	For generic drugs (me-too status)	AsunraTablet 500 mg Manufactured by: Novartis Pharma
	Name and address of API manufacturer.	Name: SYMED LABS LIMITED Unit VI Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India. GMP validity : 01-01-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Asunra Dispersible Tablet 500 mg Manufactured by: NOVARIS PHARMA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI	

	Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	4DFX0040622		
Description of Pack (Container closure system)	A White HDPE bottle with induction seal containing 30s' tablets with printed adhesive label Packs of 30s'		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TODI – 500 – 001	TODI – 500 – 002	TODI – 500 – 003
Batch Size	1500 Units	1500 Units	1500 Units
Manufacturing Date	November -2022	November -2022	November -2022
Date of Initiation	10-11-2022	10-11-2022	10-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Allmed (DML #000645) Loan Quantity: 14 kg Allmed Clearance data: Clearance date: 16-06-2022 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2. P.5.4	Please clarify the status of batch analysis report of drug products either film coated or dispersible tablets?	Film coated Rectified & attached

3.2.P.8	Please clarify the reason of negative peak in the chromatograms.	The appearance of negative peak in some of the chromatograms may be due to presence of air bubbles in the column. However, the validation data of analytical method is an evidence that we have no negative peaks during method validation. We have repeated our SOP to confirm the system before start of analysis for any peaks other than the peaks of interest.
	Please include in calculation sheets, the number of dilution of sample and standard solution to get final concentration mg/ml.	Attached as reference
	Please submit chromatograms for dissolution tests and calculation sheets.	Attached

Decision: approved with bp specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021.

1582.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt.) Ltd. (DML # 000576) 9.5 km, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	**M/s Neutro Pharma (Pvt.) Ltd. (DML # 000576) 9.5 km, Sheikhupura Road, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to 13-04-2025
	Evidence of approval of manufacturing facility	Central Licensing Board in its 287th meeting held on 24th June 2022 approved the renewal of DML of the firm including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25009 dated 13-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 18-07-2023 Slip # 88722027598
	The proposed proprietary name / brand name	Neusirox DISPERSIBLE TABLET 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dispersible tablet contains: Deferasirox ……. 500 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferasirox is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03

	Pharmaceutical form of applied drug	Dispersible tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ANSM /MHRA/FDA approved JADENU 500 mg Tablet
	For generic drugs (me-too status)	Efesir Dispersible Tablet 500 mg Manufactured by: Shrooq Pharma
	Name and address of API manufacturer.	Name: Aalidhra Pharmachem Pvt. Ltd. Address: Plot # 163 & 164, G.I.D.C, Nandesari, Dist. Vadodara, Gujarat, India. GMP validity : 08-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Exjade Dispersible Tablet 500 mg Manufactured by: NOVARTIS PHARMA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	Name: SYMED LABS LIMITED Unit VI	

	Address: SY: 744,745,750,751,752,753, Mandollagudem Village, Choutuppal Village, Choutuppal Mandal, Yadadri Bhuvanagiri District,Pincode 508204, Telangana State, India.		
API Lot No.	DEFE/III/2020/194/01		
Description of Pack (Container closure system)	White to off-white colored oblong biconvex shaped tablet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TDFA, T1-22	TODI – 500 – 002	TODI – 500 – 003
Batch Size	1500 Tablets	1500 Units	1500 Units
Manufacturing Date	06 -2022	November -2022	November -2022
Date of Initiation	10-11-2022	10-11-2022	10-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 19-08-2020 Quantity: 3 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: approved with bp specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021.

1583.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. (DML # 000856) Plot No. 35-A, Small Industrial Estate, Taxila.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Pvt.) Ltd. (DML # 000856) Plot No. 35-A, Small Industrial Estate, Taxila.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate valid till 15-08-2024
	Evidence of approval of manufacturing facility	Central Licensing Board in its 285th meeting held on 17th & 18th March 2022approved the renewal of DML including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26029 dated 17-10-2023
	Details of fee submitted	PKR 75,000/-: Dated 16-10-2023 Slip # 10148666
	The proposed proprietary name / brand name	Defrizon Tablet 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Deferiprone ……. 500 mg
	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferiprone is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Film coated Tablets
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Ferriprox ® 500 mg Tablet
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: AARTI PHARMALABS LIMITED Address: Plot # D-53, Phase II, M.I.D.C Kalyanshil RD Dombivali (East) Thane 421204 Maharashtra State, India. GMP validity : 13-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Ferriprox Tablet 500 mg Manufactured by: Cheisi USA Testing Parameters: Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: AARTI PHARMALABS LIMITED Address: Plot # D-53, Phase II, M.I.D.C Kalyanshil RD Dombivali (East) Thane 421204 Maharashtra State, India.		
API Lot No.	DFN/2302/001/034		
Description of Pack (Container closure system)	ALU-ALU blister further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	DFP-001	DFP-002	DFP-003
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	07 -2023	07 -2023	07 -2023
Date of Initiation	13-07-2023	13-07-2023	13-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 06-07-2023 Quantity: 06 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2.S.5	Please submit system suitability report along with chromatograms as per BP specification wherein resolution should be minimum 5.0 between the peaks due to impurity B and deferiprone & to ensure that retention time of deferiprone is about 12 minutes.	Submitted
3.2.P.2	Please submit details for source of Ferriprox tablet for manufacturer, batch # and date of purchase of sample.	Submitted
3.2.P.8	Please submit stability data (chromatograms, calculation sheets, raw data) for the last interval of 06 month for both accelerated and long term climatic conditions.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1584.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. (DML # 000856) Plot No. 35-A, Small Industrial Estate, Taxila.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Pvt.) Ltd. (DML # 000856) Plot No. 35-A, Small Industrial Estate, Taxila.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate valid till 15-08-2024
	Evidence of approval of manufacturing facility	Central Licensing Board in its 285th meeting held on 17th & 18th March 2022 approved the renewal of DML including Oral Liquid (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27666 dated 27-11-2023
	Details of fee submitted	PKR 75,000/-: Dated 14-11-2023 Slip # 21829184419
	The proposed proprietary name / brand name	Defrizon 100 mg/ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Deferiprone ……. 100 mg

	Pharmaco-therapeutic Group of (API)	Iron chelators. Deferiprone is in a class of medications called iron chelators. It works by attaching to iron in the body so that it can be excreted (removed from the body) in feces. ATC Code V03AC03
	Pharmaceutical form of applied drug	Film coated Tablets
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Ferriprox ® syrup
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: AARTI PHARMALABS LIMITED Address: Plot # D-53, Phase II, M.I.D.C Kalyanshil RD Dombivali (East) Thane 421204 Maharashtra State, India. GMP validity : 13-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Ferriprox Oral Solution Manufactured by: Cheisi USA Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: AARTI PHARMALABS LIMITED Address: Plot # D-53, Phase II, M.I.D.C Kalyanshil RD Dombivali (East) Thane 421204 Maharashtra State, India.

API Lot No.	DFN/2302/001/034		
Description of Pack (Container closure system)	ALU-ALU blister further packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	DFS-001	DFS-002	DFS-003
Batch Size	400 Bottles	400 Bottles	400 Bottles
Manufacturing Date	08 -2023	08 -2023	08 -2023
Date of Initiation	07-08-2023	07-08-2023	07-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 06-07-2023 Quantity: 06 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit Section approval letter / covering letter issued along with Drug Manufacturing License to confirm the approval of Tablet (General) Section of your firm by Central Licensing Board.	Submitted
3.2.S.5	Please submit system suitability report along with chromatograms as per BP specification wherein resolution should be minimum 5.0 between the peaks due to impurity B and deferiprone & to ensure that retention time of deferiprone is about 12 minutes.	Submitted
3.2.P.2	Please submit details for source of Ferriprox tablet for manufacturer, batch # and date of purchase of sample.	Submitted
3.2.P.8	Please submit stability data (chromatograms, calculation sheets, raw data) for the last interval of 06 month for both accelerated and long term climatic conditions.	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1585.	Import case	
	Name, address of Applicant / Importer	**M/s Chiesi Pharmaceuticals (Pvt.) Ltd Head Office: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg iii, Lahore.**
	Details of Drug Sale License of importer	License No: 05-352-0058-0161D Address: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg iii, Lahore. Address of godown: Ground Floor, Plot # 26, Yasir Block, New Jail Road, Behind Bilal Masjid, Kot Lakhpath, Lahore. Validity: 25-07-2023 Status: Expired
	Name and address of marketing authorization holder (abroad)	Chiesi Farmaceutica S.p.A, Via San Leonardo 96-43122, Parma, Italy.
	Name, address of manufacturer(s)	Name: Apotex Inc. – Richmond Hill Address: site 380 Elgin Mills Road East Richmond Hill, ON L4C5H2 Canada.
	Name of exporting country	Italy
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Original & Legalized Date of Legalization: 28th November 2023 CoPP: Firm has submitted original, apostilled CoPP certificate (No. 01/23/002898) dated 13-03-2023 issued by European Medicine Agency The CoPP specifies free sale status of the product in country of export along with its availability. GMP Certificate # No. 81104 Issued on 01-03-2023 Validity: 02 years from date of issuance. Certificate confirms that drug manufacturer complies with the requirement of GMP.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from Chiesi Farmaceutici S.p.A Parma, Italy, Date of Authorization: 30-10-2017 Details of entity authorized in Pakistan: M/s Chiesi Pharmaceuticals (Pvt.) Ltd Head Office: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg iii, Lahore.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 23613 Dated: 25th September 2023
	Details of fee submitted	PKR 75000/-: 26th December 2023 Slip # 42725957

	The proposed proprietary name / brand name	Ferriprox Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Deferiprone ……... 100 mg
	Pharmaceutical form of applied drug	Oral solution
	Pharmacotherapeutic Group of (API)	Iron Chelating Agent
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	250 ml
	Proposed unit price	MRP: 55000/- for 250 ml
	The status in reference regulatory authorities	This drug product to be imported is approved in EMAE, USFDA, Health Canada.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Srini Pharmaceutials (Pvt.) Ltd. Address: ChoutuppalVillage & Mandal Yadadri Bhuvanagiri District Bhongiri, Telangana, India. OR Name: Apotex Pharmachem Inc. Address: 34 Spalding Drive, Brantford, Ontario N3T 6B8 Canada..
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40º ±2 º C/75 ± 5% RH for 06 months. Real time: 25º ±2 º C/60 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	250 mL amber polyethylene terephthalate (PET) round bottle with white polypropylene child resistant cap, dosing cup further packed in unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40°C ±2°C Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 24 months Temperature: 30°C ±2°C Relative Humidity: 65% ± 5%.
Evaluation by PEC:		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.		
1586.	**Import case**	
	Name, address of Applicant / Importer	**M/s Chiesi Pharmaceuticals (Pvt.) Ltd** **Head Office: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg III, Lahore.**
	Details of Drug Sale License of importer	License No: 05-352-0058-0161D Address: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg iii, Lahore. Address of godown: Ground Floor, Plot # 26, Yasir Block, New Jail Road, Behind Bilal Masjid, Kot Lakhpath, Lahore. Validity: 25-07-2028 Status: Expired
	Name and address of marketing authorization holder (abroad)	ChiesL 175 Rcecnc,, Woods. Suite 600, Cary, NC 27518 United States of America
	Name, address of manufacturer(s)	Manufacturer details : Apotex Inc., 50 Stein way Boulevard, Etobicoke, Ontario M9W 6Y3 CANADA Packager: 4100 Weston Road, Toronto, Ontario M9L 2Y6 CANADA.
	Name of exporting country	USA
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Original & Legalized Date of Legalization: 01st April 2023 CoPP: Firm has submitted original, apostilled CoPP certificate (No. YZQ2-7RKU) dated 21-12-2022 issued by USFDA The CoPP specifies free sale status of the product in country of export along with its availability. GMP Certificate # No. 81104 Issued on 01-03-2023 Validity: 02 years from date of issuance. Certificate confirms that drug manufacturer complies with the requirement of GMP.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from Chiesi Farmaceutici S.p.A Parma, Italy, Date of Authorization: 17-03-2021

		Details of entity authorized in Pakistan: M/s Chiesi Pharmaceuticals (Pvt.) Ltd Head Office: Office No. 04, 4th floor, Askari Corporate Towers, 75/76 D-1, Main Boulevard, Gulberg III, Lahore.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. U3W-YEH-XNWN Dated: 13-12-2023
	Details of fee submitted	PKR 75000/-: 13th December 2023 Slip # 10567202297
	The proposed proprietary name / brand name	Ferriprox® Twice a Day Tablets 1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Released Tablet contains: Deferiprone ……... 1000 mg
	Pharmaceutical form of applied drug	Modified release oral tablet with enteric coating
	Pharmacotherapeutic Group of (API)	Iron Chelating Agent
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5 x 10s
	Proposed unit price	MRP: 110,000/-
	The status in reference regulatory authorities	This drug product to be imported is approved in USFDA & Health Canada.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Srini Pharmaceutials (Pvt.) Ltd. Address: ChoutuppalVillage & Mandal Yadadri Bhuvanagiri District Bhongiri, Telangana, India. OR Name: Apotex Pharmachem Inc. Address: 34 Spalding Drive, Brantford, Ontario N3T 6B8 Canada..
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40º ±2 º C/75 ± 5% RH for 06 months. Real time: 25º ±2 º C/60 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Ferriprox 1000 mg modified-release tablets are to be commercialized in blister packs, each containing 50 tablets. (Foil Silver Cold form and Foil silver plain)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40ºC ±2ºC Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30ºC ±2ºC Relative Humidity: 75% ± 5%.
Evaluation by PEC:		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.		
1587.	**Import case**	
	Name, address of Applicant / Importer	**M/s AMB HK ENTERPRISES (PVT) LTD Head Office: 2nd Floor, 60k commercial Plaza Phase 1 DHA Lahore.**
	Details of Drug Sale License of importer	License No: 05-532-0058-104514D Address: 2nd Floor, 60k commercial Plaza Phase 1 DHA Lahore. Address of godown: House # 27, Street # 4-A, Sanda Bhatian wala Gulshan e Ravi, Lahore. Validity: 08-05-2028
	Name and address of marketing authorization holder (abroad)	Globella Pharma Private Limited. Plot # 357-358, Road # 03, Gide Sachin, Surat, India.
	Name, address of manufacturer(s)	Globella Pharma Private Limited. Plot # 357-358, Road # 03, Gide Sachin, Surat, India.

	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Original & Legalized Date of Legalization: 30-04-2024 CoPP: Firm has submitted original, apostilled CoPP certificate (FG/WHO GMP/COPP/2023/2450225370) dated 22-05-2023 issued by FDAGuajarat, India. The CoPP specifies free sale status of the product in country of export along with its availability. Certificate confirms that drug manufacturer complies with the requirement of GMP and valid till 14-09-2024.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from Globella Pharma Private Limited, India. Date of Authorization: 13-07-2023 Details of entity authorized in Pakistan: M/s AMB HK ENTERPRISES (PVT) LTD Head Office: 2nd Floor, 60k commercial Plaza Phase 1 DHA Lahore.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Track ID. BAN-81B-WRMJ Dated: 16-05-2024
	Details of fee submitted	PKR 150000/-: 30-10-2023 (Slip # 2453937368)
	The proposed proprietary name / brand name	Imaticor Tablet 400 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imatinib Mesylate equivalent to Imatinib ……..... 400 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic drug
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	10’
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Givec Tablet by Novartis
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Acebright (India) Pharma Private Limited Address: No:.77D & 116/117,KIADB Industrial Area, Jigani ,Banglore-560 105, Karnataka India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40º ±2 º C/75 ± 5% RH for 06 months. Real time: 25º ±2 º C/60 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Gleevec 400 Tablet Manufacturer: Novartis pharmaceuticals Corporation
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	ALU-ALU Blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40ºC ±2ºC Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30ºC ±2ºC Relative Humidity: 75% ± 5%.
Evaluation by PEC:		
Decision: Approved as per Policy for inspection of Manufacturer abroad. **Registration Board further decided that registration letter will be issued after submission of following:** **i. Valid, Notrized CoPP to I&V Section.** **ii. Valid, letter of authorization.**		
1588.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PHARMEVO (PVT) LTD. (DML # 000504) A-29, North Western Industrial Zone, Port Qassim Karachi.**
	Name, address of Manufacturing site.	**M/s PHARMEVO (PVT) LTD. (DML # 000504)**

		A-29, North Western Industrial Zone, Port Qassim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: DYM-MTE-2Q4E Dated: 20-05-2024
	Details of fee submitted	PKR 75,000/-: 02-10-2023 (Slip # 2712684658)
	The proposed proprietary name / brand name	LinaMet XR 5+1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Linagliptin (*as immediate release coat)* …… 5 mg Metformin HCl *(as extended release core)…*1000 mg
	Pharmacotherapeutic Group of (API)	dipeptidyl peptidase-4 (DPP- 4) inhibitors / biguanides
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FDA Approved Jentadueto XR Tablet
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Please submit complete 06th month stability study data along with chromatograms, raw data and calculation sheets for both accelerated and real time cloimatic conditions.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1589.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PHARMEVO (PVT) LTD. (DML # 000504) A-29, North Western Industrial Zone, Port Qassim Karachi.**
	Name, address of Manufacturing site.	**M/s PHARMEVO (PVT) LTD. (DML # 000504) A-29, North Western Industrial Zone, Port Qassim Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: NH9-J6G-471A Dated: 20-05-2024
	Details of fee submitted	PKR 75,000/-: 02-10-2023 (Slip # 022381133177)
	The proposed proprietary name / brand name	LinaMet XR 2.5+1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Linagliptin (*as immediate release coat)* …… 2.5 mg Metformin HCl *(as extended release core)…*1000 mg
	Pharmacotherapeutic Group of (API)	dipeptidyl peptidase-4 (DPP- 4) inhibitors / biguanides

	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's 10's 14's 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FDA Approved Jentadueto XR Tablet
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Please submit complete 06th month stability study data along with chromatograms, raw data and calculation sheets for both accelerated and real time cloimatic conditions.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 05: Missing Decision in 331st meeting of DRB for the drug product at Sr. # 1524

The following case of the firm was presented in 331st meeting of Drug Registration Board at Sr. # 1524, however, the decision of the Board couldn't be recorded in the minutes of the meeting. Therefore, case has been again placed before the Board for consideration please.

1590.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winthrox Laboratories Pvt. Ltd K-219 A, SITE Super Highway, Phase II, Karachi. (DML # 000807)**
	Name, address of Manufacturing site.	**M/s Winthrox Laboratories Pvt. Ltd K-219 A, SITE Super Highway, Phase II, Karachi. (DML # 000807)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	cGMP inspection report dated 30th January 2022 rated overall GMP compliance level "Good"
	Evidence of approval of manufacturing facility	Grant of Renewal of DML by CLB dated 08-06-2021 specifying Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14293 dated 24-05-2022
	Details of fee submitted	PKR 30,000/-: Dated 23-09-2021 Slip # 0987872724
	The proposed proprietary name / brand name	ONDESTY 8mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron HCl.$2H_2O$ equivalent to Ondansetron ……..8mg
	Pharmacotherapeutic Group of (API)	Selective 5-HT3 receptor antagonist / antiemetic

	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOFRAN® USFDA approved formulation
	For generic drugs (me-too status)	Onset® approved for M/s Pharmedics
	Name and address of API manufacturer.	Name: M/s Anugraha Chemical, India Address: D-47, D48, D49, D50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur Benglaru, Dist Benglaru, Rural 561203, India GMP Validity: 09-04-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Onset 8mg Tablets Manufactured by: Pharmedics, Lahore Batch # 325 | Mfg. date: 04/2021 Testing parameters: USP Specifications. **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference products. Onset® has been used as comparator product because it is well established brand in Pakistan approved by DRAP.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Anugraha Chemical, India Address: D-47, D48, D49, D50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur Benglaru, Dist Benglaru, Rural 561203, India		
API Lot No.	AOND-20017		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	PLT-01	PLT-02	PLT-03
Batch Size	1.15 KG	1.15 KG	1.15 KG
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	21-03-2021	21-03-2021	21-03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet, for which the inspection was conducted on 14-03-2019 and the report was presented in 289th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice Clearance Date: 26-02-2021 Quantity: 5KG Invoice No: EXP-22
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of the Evaluator:

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 06: Deferred cases of Form 5 / Form 5-D with stability studies.

1591.	**Name and address of manufacturer / Applicant**	**M/s Fynk Pharmaceuticals (DML # 000494)** **19Km GT Road, Kalashah Kaku, Lahore**
	Diary No. Date of R& I & fee	Dy. No:2354; Rs. 20,000/- Dated: 30-05-2016
	Brand Name +Dosage Form + Strength	E-Rox Tablet 500mg/20mg
	Composition	Each film coated tablet contains: Naproxen (enteric coated core) …… 375 mg Esomeprazole as magnesium trihydrate (immediate release coat)…… 20 mg
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non Steroids - Priopionic Acid Derivatives
	Type of Form	Form 5
	Finished product Specifications	Innovator Specification
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA approved VIMOVO®
	Me-too status	Brand Name: Proxen-ES DR 500mg/20mg Tablet. Manufacturer: M/s Martin Dow
	GMP status	Last Inspection report 07-09-2021, firm had maintained conformance to GMP compliance in the manufacturing and quality control operations.
	Decision of 274th meeting DRB:	***Deferred for following submissions*** • ***Application on Form 5-D*** • ***Differential fee PKR 30,000/-*** • ***Accelerated and real time stability study data along with relevant documents as per the requirements of 251st meeting of Registration Board*** • ***GMP inspection report conducted within a period of last 1 year.***

STABILITY STUDY DATA

Manufacturer of API	**Naproxen** **Name:** HY-GRO Chemicals India. **Address:** Plot # 174, progressive Industrial Society, Bollaram Village, Jinnaram Mandal, Sangareddy Dist. Telangana, India. **GMP validity:** 04-04-2025 **Esomeprazole Magnesium Tri-hydrate** **Name:** Metro ChemicalAPI Pvt. Ltd. India. **Address:** Unit # 01, Plot # 62/C/6, Pipeline Road, Phase – I, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri , India. **GMP validity:** 29-09-2024	
API Lot No.	**Naproxen**	**Esomeprazole Magnesium Tri-hydrate**
	NAP-2022/05/26	ESM/2203090
Description of Pack (Container closure system)	Pale yellow coloured oblong, biconvex, modified release tablets containing 500 mg enteric coated Naproxen and 20 mg film coated seal of esomeprazole, plain on both sides , blistered in 130 mm ALU-ALU, aluminium foil and packed in outer unit carton with packing of 10's.	
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%	

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	**ERX-PB-018001**	**ERX-PB-018001**	**ERX-PB-018001**
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	12-07-2022	12-07-2022	12-07-2022
No. of Batches	03		
Date of Submission	24-11-2022 (33857)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	**Naproxen** Real time conditions on Zone IV-A,36 months Accelerated conditions -→ 06 months **Esomeprazole Magnesium Tri-hydrate** Real time conditions on Zone IV-A,72 months Accelerated conditions -→ 06 months
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	**Naproxen** **Invoice #** H/E/22-23/21 **Dated:** 08-05-2022 **Quantity:** 3 kg **Esomeprazole Magnesium Tri-hydrate** **Invoice #** AE/21-22/0562 **Dated:** 07-04-2022 **Quantity:** 0.1 Kg
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not required
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted

xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

S #	Observations	Reply of the firm
	Please submit differential fee of PKR 30000/-	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 07: Deferred cases of Form 5.

1592.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714) Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Medifax Plus ointment
	Composition	Each gram of ointment contains: Polymixine B sulphate… …. 10000 units Bacitracin Zinc …… 500 units Lignocain …….. 40 mg
	Diary No. Date of R& I & fee	Dy. No 2485 dated 20-06-2011 Rs. 8,000/- (Form 5) Rs. 12000/- dated 27-01-2020
	Pharmacological Group	Antipruritics
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved "Ozonol"
	Me-too status	Polyfax Plus ointment
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator.	
	Decision of 333rd DRB meeting: The Board decided to refer the case to sub committee for pharmaceuticals.	
	Remarks: the RRA status has been confirmed.	
	Decision: Approved • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
1593.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)**

		Plot No. 2 Street No. 4 National Industrial Zone Rawat.
	Brand Name +Dosage Form + Strength	Tablet Mecobin 500 mcg
	Composition	Each film coated tablet contains: Mecobalamin ……. 500 mcg
	Diary No. Date of R& I & fee	Dy. No 2795 dated 23-06-2011 Rs. 8,000/- *(Form 5)* *Rs. 20000/- dated 27-01-2020*
	Pharmacological Group	Vitamins supplement
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Registered in Pakistan
	GMP status	GMP certificate issued by DRAP Validity: not provided
	Remarks of the Evaluator.	Firm has changed the dosage form of applied formulation from capsule to tablet by submitting differential fee of PKR 20000/- on 27-01-2020 however, the complete fee of PKR 20000/- required for FORM 5 application is still deficient of PKR 12000/- while the differential fee is also PKR30000/- Formulation in film coated not verified from RRA countries. USP specification not found for this dosage form as claimed by the firm.
	Decision in 333rd meeting of DRB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
	Remarks of the Evaluator: Firm has re-submitted Form-5 and explained that the formulation changed after submission of fee was applied as under Each sugar coated tablet contains Mecobalamin ……....500 mcg (JP Specification) The formulation now submitted by firm is justified and available in RRA and me-too status also confirmed.	
	Decision: Approved as under **Each sugar coated tablet contains** **Mecobalamin ……....500 mcg** **(JP Specification**) •	
1594.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Frecid plus liquid 500mg/267mg
	Composition	Each 10ml liquid suspension contains: Sodium alginate…….500mg Sodium bicarbonate…….267mg
	Diary No. Date of R& I & fee	Dy No.1614; 30-11-2016; Rs. 20000/-
	Pharmacological Group	Haemostatic agent/Alkalizing agent
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	France approved formulation

	Me-too status	Registered in Pakistan
	GMP status	GMP inspection conducted on 07-12-2017 shows that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator.	
	Decision of 297th meeting of DRB: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Approved	
1595.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals. (DML # 000839)** **Plot No. A-2, Street S-5, RCCI, Rawat.**
	Brand Name +Dosage Form + Strength	Epiwell 250mg Oral Liquid syrup‘
	Composition	Each 5 ml contains: Sodium Valproate equivalent to Valproic Acid ……. 250mg
	Diary No. Date of R& I & fee	Dy. No. 2473 dated 08-06-2016 Rs. 20,000/- *(Form 5)*
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Depakene 250mg/5ml
	Me-too status	Epival Syrup 250mg/5ml
	GMP status	GMP certificate issued on the basis of inspection report conducted on 19-01-2022.
	Remarks of the Evaluator.	*The case was deferred in 260th meeting of DRB for following shortcomings:* *“Deferred for confirmation of approval status of formulation by reference regulatory authorities and Pakistan”*
	Decision: Approved	
1596.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals. (DML # 000839)** **Plot No. A-2, Street S-5, RCCI, Rawat.**
	Brand Name +Dosage Form + Strength	Re-Dose 175mg /5ml Oral Dry suspension
	Composition	Each 5ml of reconstituted suspension contains: Erdosterine ……. 175 mg
	Diary No. Date of R& I & fee	Dy. No. 2785 dated 08-06-2016 Rs. 20,000/- *(Form 5)*
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	35ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMAE approved Erdosterine 175mg/5mlby Edmond Pharma Italy
	Me-too status	Dostin By Brooks pharmaceuticals
	GMP status	GMP certificate issued on the basis of inspection report conducted on 19-01-2022.
	Remarks of the Evaluator[3].	*The case was deferred in 260th meeting of DRB for following shortcomings:* *“Deferred for confirmation of approval status of formulation by reference regulatory authorities and Pakistan.”*
	Decision: Approved	

1597.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals. (DML # 000839)** **Plot No. A-2, Street S-5, RCCI, Rawat.**
	Brand Name +Dosage Form + Strength	Amikan Liquid injection 100 mg
	Composition	Each 2ml vial contains: Amikacin (as Sulphate) ……. 250 mg
	Diary No. Date of R& I & fee	Dy. No. 2785 dated 08-06-2016 Rs. 20,000/- *(Form 5)*
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	35ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Dostin By Brooks pharmaceuticals
	GMP status	GMP certificate issued on the basis of inspection report conducted on 19-01-2022.
	Remarks of the Evaluator[3].	*The case was deferred in 260th meeting of DRB for following shortcomings:* *"Deferred for proof of approval of same formulation (250mg/2ml) by reference regulatory authorities."* Remarks: Firm has now submitted reply that there was mistake in formulation and revised the form 5 along with prescribed fee of PKR 30,000/- *(Challan # 457232274129)* for revision of strength as under. Brand Name: Amikan Liquid injection 100 mg Each 2 ml vial contains Amikacin (as sulphate) ……. 100mg (50 mg/ml) RRA: USFDA approved formulation *(discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**)* Me Too: registered for Zafa Pharma.
	Decision: Approved **Each 2 ml vial contains** **Amikacin (as sulphate) ……. 100mg (50 mg/ml)**	
1598.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan (Pvt) Ltd. (DML # 000051)** **20 Km Ferozepur Road Lahore.**
	Brand Name +Dosage Form + Strength	Tramic 500 mg Injection
	Composition	Each 5ml of solution in ampoules contains Tranexamic acid……. 500 mg
	Diary No. Date of R& I & fee	Dy. No. 17185 dated 05-10-2017 Rs. 20,000/- dated 02-10-2017
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Transamin by Hilton
	GMP status	Latest GMP status required
	Remarks of the Evaluator[3].	Decision of 333rd meeting of DRB:

		"Deferred for the submission section approval from Licensing Division and the GMP certificate or GMP inspection report during the last 3 years. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board." Remarks: GMP Validity of the firm: 13-09-2022 Section Approval: Tablet (General) Section included in renewal of DML in 275th meeting of Central Licensing Board. Verification of fee challan: not yet done.
	Decision: Approved subject to verification of challan.	
1599.	**Name and address of manufacturer / Applicant**	**M/s McOlson Research Laboratories (Pvt) Ltd. (DML # 0000664)** **26-Km Lahore Sharakpur Road District Sheikhupura.**
	Brand Name +Dosage Form + Strength	Tablet Koncept 20 mg
	Composition	Each Enteric Coated tablet contains Esomeprazole Magnesium Tri-hydrate equivalent to Esomeprazole …… 20 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* Dy. No. 1420 dated 15-01-2011 Rs.8000/- dated 13-01-2011 (photocopy) Rs.12000/- dated 24-11-2014 (photocopy)
	Pharmacological Group	Antianaemics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nexium Control 20 mg by AstraZeneca
	Me-too status	Fasteso 20 mg Tablet by PharmEvo (Reg # 33721)
	GMP status	GMP Certificate validity: 03-06-2024
	Decision of 333rd meeting of DRB: *Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.* *Please submit details of manufacturing process keeping in view the flow, lubrication, disintegration, organoleptic properties, compressibility & compatibility.* *Please justify that why methyelene chloride has been part of your coating tablet while ICH guidelines categorically advise to avoid use of organic solvent in formulation.* *Also provide evidence of methyelene chloride being part of any same formulation approved in countries with reference regulatory authorities declared by DRAP.* *Please submit details of the testing parameters and its reference pharmacopeia / specifications*	
	Remarks of the Evaluator. Firm has submitted undertaking that they will not use the Methyelene Chloride in coating formulation. Firm replaced methylene chloride with IPA & Methanol. However, it is pertinent to mention here that innovator product use opadry film coating technique instead of organic solvents. Firm submitted Fee of PKR 7500/- for change in formulation. Firm submitted the specification which contains all the test as per innovator specification.	
	Decision: Approved **The firm will make sure to observe personal protective parameters provided under MSDS of IPA to be used in coating of drug product.** **The QA/LT division is requested to monitor this direction through its field offices and report in the next GMP inspection of the firm.**	

Item No. 08: Deferred cases of Form 5F

1600.	**Case deleted due to repitition**	
1601.	**Import Molecules (deferred in 333rd meeting of DRB)**	
	Name, address of Applicant / Importer	**M/s AMB HK ENTERPRISES Pvt Ltd. Pakistan (Importer)** **Head office: 60-K, Commercial Phase-I, DHA Contonement Punjab**
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: H#27, ST#4-A, Sanda Bhatian wala Gulshan Ravi Lahore. Validity: 08-05-2028. Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad) / Exporter.	LIAONING HONGYUAN PHARMACEUTICAL CO. LTD. Floor 1, Building 2, Standardized Workshop, No. 18 Shennong Dajie, Ben Xi High-tech Industrial Development Zone, Liao Ning Province China.
	Name, address of manufacturer(s)	Hebei Shanmushi Pharmaceutical Co. Ltd. No. 123, Zhayuan Road, Zhao County, Shijiazhuang City, Hebei Province China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Legalized documents submitted by firm Date of Legalization: 03-11-2022 CoPP: Firm has submitted CoPP certificate (No.20220316) dated 23-08-2022 issued by Hebei Province Drug Administration, China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 15-06-2024 GMP: The firm has also Drug Production License issued by Hebei Food & Drug Administration, China.
	Details of letter of authorization / sole agency agreement	Sole Agreement submitted by firm. Contract # SMS-HY-20220827 Dated: 27th August 2022 M/s AMB HK ENTERPRISES Pvt Ltd declared as sole / exclusive agent in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import

		☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 30344 Dated: 26th October 2023
	Details of fee submitted	PKR 150000/-: 05-10-2022 Slip # 0672569338
	The proposed proprietary name / brand name	Savotane 250 ml Liquid for inhalation
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml contains Sevoflurane …….... 100% w/v
	Pharmaceutical form of applied drug	Volatile Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anesthetic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	250ml per bottle
	Proposed unit price	PKR 7100 per 250 ml bottle
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Product name: Sevoflo Solution Importer: Allmed (Pvt.) Ltd Reg. # 114071
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hebei Shanmushi Pharmaceutical Co. Ltd. No. 123, Zhayuan Road, Zhao County, Shijiazhuang City, Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40ºC ± 2°C / RH 75% ± 5% for 06 months. Real time: 30ºC ± 2°C / RH 75% ± 5% for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Name: ULTANE® Solution for inhalation Manufacturer: Maruishi Pharmaceutical Co. Ltd. Japan.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type III Amber Glass Bottles, Poly-seal Closure.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40°C ±2°C Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30°C ±2°C Relative Humidity: 75% ± 5%.

Evaluation by PEC: (deferred in 333rd meeting of DRB)

Section	Observations	Status
1.3.4	Please submit legalized GMP certificate and Certificate of Pharmaceutical product.	Submitted
	Please submit valid drug distribution license of importer which should be in force till date.	Submitted

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Registration Board further decided that registration letter will be issued after submission of following:

i. Valid, Legalized CoPP to I&V Section.

ii. Valid, letter of authorization.

1602.	***Deferred caseof 322nd meting of DRB***	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Jaskan Pharmaceutical Private Limited (DML # 796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Jaskan Pharmaceutical Private Limited (DML # 000796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 283rd meeting approved the "Dry Powder Cephalosporin Injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 9668 dated 15/04/2022
	Details of fee submitted	PKR 30,000/-: dated 30-03-2022
	The proposed proprietary name / brand name	Cefbo Injection 1gm IM/IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone as Sodium……. 500mg Sulbactam as Sodium.....500mg
	Pharmaco-therapeutic Group of (API)	Sterile powder for solution for injection
	Pharmaceutical form of applied drug	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP (Japanese Pharmacopoeia)
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA) of Japan.
	For generic drugs (me-too status)	Sulzone 1.0gm Injection M/s Biocare Pharmaceutical by Dawnrays Pharmaceutical Co,Ltd., Reg. No. 028468
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24s months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(9001HK81NG,9002HK81NG, 9003HK81NG)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Sulzone 1.0gm Injection M/s Biocare Pharmaceutical by Dawnrays Pharmaceutical Co, Ltd., by performing quality tests

		(Identification, Assay, Dissolution, Uniformity of dosage form etc). (B:210312101)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China		
API Lot No.	9001HK81NG		
Description of Pack (Container closure system)	Type I 15mL glass vial with fluorobutyl rubber stopper and green color flip off aluminum seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	LD 01	LD 02	LD 03
Batch Size	100Vials	100Vials	100Vials
Manufacturing Date	02-10-2021	02-10-2021	02-10-2021
Date of Initiation	18-10-2021	18-10-2021	18-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	ADC attested Invoice NO JTRF210911-MQ Diary No. 14373/204DRAP Dated 24-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S#	Observations	Reply of the firm
i.	Please provide valid copy of GMP certificate of manufacturer of Drug substance.	GMP Validity: 25-06-2025
ii.	Provide Analytical method verification studies performed by drug product manufacturer for drug substance.	Submitted

iii.	Pharmaceutical equivalence should be established against the Refrence innovator's product while you performed the studies against mee-too product.	No product of Refrence innovators was availabe in pakistan. Sulzone Brand approved by DRAP is the Brand leader in pakistan by Suzhou Dawnrays Pharmaceutical Co, LTD and Biocare Pharmaceutica import it. so we have established equivalence testing against this brand.
iv.	As per specifications of drug substance and COA from the drug substance manufacturer, the water content must be less than 4% and 1.9% water content has been determined while according to the specifications as provided by J.P o f finished product , the water content should be less than 1%.Keeping in view the allowed percentage of water content , please clarify that how would the finished product comply with the specification as described for JP for water content determination if the drug substance has a content higher than 1%.	In stability studies data the three batches namely 9001HK81NG, 9001HK81NG and9001HK81NG are used. The Batch No 1088 E J 81 N E used for drug product manufacturing has the moisture content 0.9%. We have used this drug substance for drug product manufacturing. Documents are attached for your kind considration.
v.	The stability data is submitted till 3rd month time point. Please provide stability studies till 6th month time point.	Submitted
vi.	Please justify the stability studies without the performance of sterility and bacterial endotoxins.	Submitted
vii.	Provide and justify the quantity of drug substance used for potency adjustment and also provide complete calculations.	Assay on anhydrous basis Cefoparazone =48.25% Sulbactam =48.16% Assay on as is basis Cefoparazone =47.82% Sulbactam =47.73% Calculation for subactam Factor =50/47.73=1.047 Quantity=500X1.047=523.78 mg As sulbactam is on lower side so cefoparazone would be same as =523.78 mg Total quantity for one vial is=1047.56 mg Or 1048 mg Quantity for 100 vials =0.1048 kg.
viii.	Compliance record of HPLC software 21CFR and audit trail reports on product testing.	We are using EZE chrome HPLC software which is 21CFR compliance audit trail is attached.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021 and latest GMP certificate / inspection report conducted within a period of last 3 years**

1603.	**Deferred cases of 322nd meting of DRB**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Jaskan Pharmaceutical Private Limited (DML # 796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Jaskan Pharmaceutical Private Limited (DML # 796)**

		Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 283rd meeting approved the "Dry Powder Cephalosporin Injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9669 dated 15/04/2022
	Details of fee submitted	PKR 30,000/-: dated 30-03-2022
	The proposed proprietary name / brand name	Cefbo Injection 2gm IM/IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone as Sodium……. 1000mg Sulbactam as Sodium.....1000mg
	Pharmaco-therapeutic Group of (API)	Sterile powder for solution for injection
	Pharmaceutical form of applied drug	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP (Japanese Pharmacopoeia)
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA) of Japan.
	For generic drugs (me-too status)	Sulzone 2.0gm Injection M/s Biocare Pharmaceutical by Dawnrays Pharmaceutical Co,Ltd., Reg. No. 028469
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24s months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(9001HK81NG,9002HK81NG, 9003HK81NG)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Sulzone 2.0gm Injection M/s Biocare Pharmaceutical by Dawnrays Pharmaceutical Co, Ltd., by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form etc). (B:210712201)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China		
API Lot No.	9001HK81NG		
Description of Pack (Container closure system)	Type I 15mL glass vial with fluorobutyl rubber stopper and green color flip off aluminum seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	LE 01	LE 02	LE 03
Batch Size	100Vials	100Vials	100Vials
Manufacturing Date	02-10-2021	02-10-2021	02-10-2021
Date of Initiation	18-10-2021	18-10-2021	18-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	ADC attested Invoice NO JTRF210911-MQ Diary No. 14373/204DRAP Dated 24-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the

		HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S#	Observations	Reply of the firm
	Please provide valid copy of GMP certificate of manufacturer of Drug substance.	GMP Validity: 25-06-2025
	Provide Analytical method verification studies performed by drug product manufacturer for drug substance.	Submitted
	Pharmaceutical equivalence should be established against the Refrence innovator's product while you performed the studies against mee-too product.	No product of Refrence innovators was availabe in pakistan. Sulzone Brand approved by DRAP is the Brand leader in pakistan by Suzhou Dawnrays Pharmaceutical Co, LTD and Biocare Pharmaceutica import it. so we have established equivalence testing against this brand.
	As per specifications of drug substance and COA from the drug substance manufacturer, the water content must be less than 4% and 1.9% water content has been determined while according to the specifications as provided by J.P o f finished product , the water content should be less than 1%.Keeping in view the allowed percentage of water content , please clarify that how would the finished product comply with the specification as described for JP for water content determination if the drug substance has a content higher than 1%.	In stability studies data the three batches namely 9001HK81NG, 9001HK81NG and9001HK81NG are used. The Batch No 1088 E J 81 N E used for drug product manufacturing has the moisture content 0.9%. We have used this drug substance for drug product manufacturing. Documents are attached for your kind considration.
	The stability data is submitted till 3rd month time point. Please provide stability studies till 6th month time point.	Submitted
	Please justify the stability studies without the performance of sterility and bacterial endotoxins.	Submitted
	Provide and justify the quantity of drug substance used for potency adjustment and also provide complete calculations.	Submitted
	Compliance record of HPLC software 21CFR and audit trail reports on product testing.	We are using EZE chrome HPLC software which is 21CFR compliance audit trail is attached.

Decision: approved with innovator specification.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification no.f.7-11/2012-b&a/drap dated 07-05-2021 and GMP certificate / inspection report conducted within a period of last 3 years.**		
1604.	***Deferred cases of 316th meting of DRB***	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Jaskan Pharmaceutical Private Limited (DML # 796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Jaskan Pharmaceutical Private Limited (DML # 000796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 283rd meeting approved the "Injectable (Vial) (General) (LVP) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27887 dated 08/09/2021
	Details of fee submitted	PKR 30,000/-: dated 16/09/2021
	The proposed proprietary name / brand name	Jazolin 600mg/300mL Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 300 mlVial contains: Linezolid……. 600mg (2 mg/ml)
	Pharmaco-therapeutic Group of (API)	Solution for IV infusion
	Pharmaceutical form of applied drug	Antibiotic/Oxazolidinone
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zyvox 2mg/mL solution for infusion, MHRA Approved.
	For generic drugs (me-too status)	Nezkil 600mg Infusion by M/s S.J.&G Fazul Ellahie Pvt. Ltd. Reg. No. 48804
	Name and address of API manufacturer.	M/s Optrix Laboratories Private Limited, Survey No. 145/A & 147. Ramalingampally (V), Bommalaramaram Minutes of 316th

		meeting of Registration Board (15-18 March, 2022) | 845 (M), Yadadri-Bhuvanagiri (Dist) 508126, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OT-LID-S2-002/16, OT-LID-S2-003/16, OTLID-S2-004/16)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence testing is conducted against Nezkil 600mg Infusion by M/s S.J.&G Fazul Ellahie Pvt. Ltd. by performing quality test.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Optrix Laboratories Private Limited Survey No. 145/A, 145/AA & 47, Ramalingapally (V), Bommala Ramaparam (M), Yadadri Bhuvanagiri (Dist.), 508126, India.		
API Lot No.	OT-LTD/07/20/036		
Description of Pack (Container closure system)	Type I Glass vial with rubber stopper and flip off aluminium seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	KQ-01	KQ-02	KQ-03
Batch Size	50 vial	50 vial	50 vial
Manufacturing Date	04/2021	04/2021	04/2021
Date of Initiation	05/04/2021	05/04/2021	05/04/2021

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of attested invoice (vide diary No. 12780 dated 31/08/2021) No. 21220T135/EXP dated 27/08/2021 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator: *(deferred in 322nd meeting of DRB)*

S#	Observations	Reply of the firm
	Clarification is needed since the UV-spectrophotometric method of analysis is used for testing of drug substance as well as for drug product while the method from drug substance is HPLC method.	We have analysed the drug substance by HPLC method under your guidance (USP Specification). Documents are attached.
	Submit the analytical method verification studies including specificity, accuracy and precision for drug substance performed by drug product manufacturer. Furthermore, provide the analytical method for drug substance used for routine testing.	Attached
	Provide valid copy of GMP/DML of drug substance manufacturer.	DML. Valid till 02/06/2025 GMP. Valid
	Please provide detail calculations for quantity to be dispensed per vial considering the actual potency of Linezilod since "loss on drying has not been considered nor the percentage for LOD is mentioned in COA of relevant batch used for development.	Since the LOD is 0.08% Potency of the drug substance is on anhydrous basis 99.53% Potency of the drug substance as is basis is 99.45% As is basis= anhydrous basis (100−LOD) 100 So the quantity per batch is 0.060kg That is as in our BMR. COA attached.
	The stability data is submitted till 3rd month time point, please provide stability studies till 6th month time point.	Attached
	Provide documents confirming import of the drug substance used in the manufacturing of trial batches.	Invoice NO 0914010646 DRAP NO.13174/2021/DRAP dated 01-09-2021 Copy Attached
	Clarification is required since pharmaceutical equivalence is established against Nezkil 600mg Infusion By M/s S.J &G Fazul Ellahie Pvt Ltd while the studies should be carried out against the reference innovator's product.	Zyvox infusion by Pfizer is not available in market ,we established pharmaceutical equivalence against Nezkil 600mg Infusion By M/s S.J &G Fazul Ellahie Pvt Ltd.Approved by DRAP

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1605.	***Deferred cases of 316th meeting of DRB***	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Jaskan Pharmaceutical Private Limited (DML # 796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Jaskan Pharmaceutical Private Limited (DML # 000796) Plot No 50 Sunder Industrial Estate LahorePlot # 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on the basis of inspection report conducted on 13th January 2022.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 283rd meeting approved the "Injectable (Vial) (General) (LVP) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33168 dated 21-12-2021
	Details of fee submitted	PKR 30,000/-: dated 18-11-2021
	The proposed proprietary name / brand name	Levokan Infusion 500mg/ 100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml Vial contains: Levofloxacin as hemihydrate.....500mg
	Pharmaco-therapeutic Group of (API)	Sterilized Liquid for Infusion
	Pharmaceutical form of applied drug	Quinolone antibacterial/fluoroquinolones
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Leflox Infusion 500mg/100ml Getz Pharma Pakistan Registration No: 024664
	Name and address of API manufacturer.	Zhejiang Starry Pharmaceutical Co., Ltd. (Starry) No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, China 317300

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (C019-0912001, C019-1004001, C019-1004003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence testing is conducted against Nezkil 600mg Infusion by M/s S.J.&G Fazul Ellahie Pvt. Ltd. by performing quality test.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Starry Pharmaceutical Co., Ltd. (Starry) No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, China 317300		
API Lot No.	C008-2005306		
Description of Pack (Container closure system)	Type I Glass vial with rubber stopper and flip off aluminium seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	KL 01	KL 02	KL 03
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	19-05-2021	19-05-2021	19-05-2021
Date of Initiation	05-07-2021	05-07-2021	05-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of attested invoice (vide diary No. 12780 dated 31/08/2021) No. 21220T135/EXP dated 27/08/2021 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator: *(deferred in 322nd meeting of DRB)*

S#	Observations	Reply of the firm
	Submit complete analytical method for routine analysis of drug substance by drug product manufacturer	Submitted
	Analytical method verification/validation studies including specificity, precision and accuracy performed by drug product manufacturer.	Submitted
	It is not clear from the COA of Levofloxacin Hemihydrate drug substance used for development of the applied product whether the assay value is calculated on as Is basis or it is on anhydrous basis. Please clarify.	Submitted
	COA of reference standard used is required.	Submitted
	Since the real time stability studies have not been conducted according to the conditions of zone IV-A. Therefore real time stability studies according to zone IV-A is required or otherwise submission of record of data logger for monitoring of temperature and humidity during transportation and stability studies of finished product for 6 months along with the impurity testing.	stability studies of both drug substance and drug product have been conducted according to the conditions of zone IV-A. Data Attached
	The official monograph of levofloxacin hemidrate drug substance is available is USP and it describes HPLC method for analysis while UV-visible spectroscopic method is developed for analysis of drug product. Please provide justification for adopting UV method for analysis instead of HPLC method keeping in view that the HPLC can be developed in accordance with available USP monograph of drug substance.	HPLC method is revised instead of U V method Data is attached.
	The Submitted stability study data is of 3 months please submit stability data including accelerated and real time for 6 months.	Submitted
	Provide justify the quantity of drug substance used for potency adjustment and also provide complete calculations.	Potency of levofloxacin hemihydrate as is basis=98.35 Factor for potency =1.0167 Factor for levofloxacin hemihydrate=1.0249

		levofloxacin hemihydrate =500X1.0167X1.0249=521.00 mg In BMR it was written 0.050kg instead of 0.052.we regret for the mistake.
	Provide documents for procurement of drug substance along with the API manufacturing approval/GMP of drug Substance manufacturer	Submitted

DECISION: APPROVED WITH INNOVATOR SPECIFICATION.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deferred in 333rd meeting of Drug Registration Board

1606.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt.) Ltd. (DML # 000805) 36-km, Lahore – Gujranwala Road, Khori Dstrict Sheuikhupura.**
	Name, address of Manufacturing site.	**M/s Bajwa Pharmaceuticals (Pvt.) Ltd. (DML # 000805) 36-km, Lahore – Gujranwala Road, Khori Dstrict Sheikhupura.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid till 13-02-2025
	Evidence of approval of manufacturing facility	Section granted by CLB in 282nd meeting
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22881 dated 12-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 19-07-2022 Slip # 871109892
	The proposed proprietary name / brand name	Sodium Valproate 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Sodium Valproate equivalent to Valproic acid…… 500mg/5ml
	Pharmacotherapeutic Group of (API)	Anti- Epileptics / Anti-Convulsants
	Pharmaceutical form of applied drug	Clear Colourless Solution for Injection packed in clear glass ampoule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	5mlx1's, 5mlx5's, 5mlx10's,
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	DEPACON® Manufactured by: Hospira, Inc.. for AbbVie Inc. Approved by: USFDA
	For generic drugs (me-too status)	Epival by Abbot Laboratories Reg# 076295
	Name and address of API manufacturer.	Name: Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkhazi Post Madhuranthagam Taluk Kancheepuram District Tamil Nadu 603 303, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Epival Manufactured by: Abbot Laboratories Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		Name: Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkhazi Post Madhuranthagam Taluk Kancheepuram District Tamil Nadu 603 303, India
API Lot No.		SDMNF20339
Description of Pack (Container closure system)		Clear glass ampoule, with red printing arrange in PVC tray and packe din Bleach card unit box with leaflet.
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period		Real time: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	SV-0121	SV-0221	SV-0321
Batch Size	200 Ampoules	200 Ampoules	200 Ampoules
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	22-02-2021	23-02-2021	23-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 0.050kg **Dated:** 19-01-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit valid GMP Certificate of API supplier issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Innovator specifications are not acceptable after publication of monograph in official Pharmacopeia. Please submit Pharmaceutical equivalence studies as per testing procedure provided in monograph of official Pharmacopeia.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Innovator specifications are not acceptable after publication of monograph in official Pharmacopeia. Please submit stability data for the three batches for all the test mentioned in monograph of official pharmacopeia and perform assay of drug product on HPLC and submit data accordingly.	• Firm clarified that the results of analysis using HPLC & UV spectrophotometer are comparable with RSD = 0.329. • They also mentioned that all the results mentioned in previously submitted report with innovator specifications falls under the limits defined in USP specifications and accordingly submitted stability sheets of 03 batches with limits of testing parameters as per USP specifications. • They have submitted the batch analysis data of the above mentioned stability which has been recently tested now on HPLC and chromatograms have been submitted along with

		calculation sheets ensuring that product is stable even after 24 months. • Now they requested to consider the approval of their formulation on the basis of the batch analysis report recently conducted on stability batches as per USP pharmacopeia and submitted undertaking that they will follow HPLC method of USP pharmacopeia for onward testing of their drug product for commercial batches.

Decision of 333rd meeting of Drug Registration Board: Deferred for submission of stability study data of three batches of drug product as per the analytical testing method & specifications provided monograph of drug product in the latest edition of USP pharmacopeia.

Remarks of the Evaluator:

Firm has now submitted stability data of 06th month for accelerated as well as real time climatic condtions, as per requirement of monograph of USP Pharmacoeia which has been evaluated as under:

STABILITY STUDY DATA			
Manufacturer of API	Name: Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkhazi Post Madhuranthagam Taluk Kancheepuram District Tamil Nadu 603 303, India		
API Lot No.	SDMNF20339		
Description of Pack (Container closure system)	Clear glass ampoule, with red printing arrange in PVC tray and packe din Bleach card unit box with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	SV-0191	SV-0192	SV-0193
Batch Size	200 Ampoules	200 Ampoules	200 Ampoules
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	26-10-2023	26-10-2023	26-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1607.	***Contract Manufacturing case deferred in 333rd meeting of DRB***	
	Contract Giver **Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals (DML # 000574)** **Plot No 3 Block –A Phase-I-II Industrial Estate Hattar.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s WeatherFolds Pharmaceuticals** **(DML # 000644)** **Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3927 (dated: 10-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 09-01-2023 (Invoice # 4704293740)
	The proposed proprietary name / brand name	Vonp-AS 10/100 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin as Enteric Coated Tablet ….. 100 mg **With drug coating of** Vonoprazan as fumarate as immediate release layer …… 10 mg
	Pharmaceutical form of applied drug	Yellow colour round in shape, film coated tablets (Aspirin delayed release and Vonoprazan immediate release tablets)
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA approved **Cabpirin ®** by Otsuka.
	For generic drugs (me-too status)	N/A
	Section Approval Letter from Licensing Division of DRAP	Tablet (General) Section, Approval by Central Licensing Board in its 222nd meeting held on 04th March 2010.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 27-10-2025
	Name and address of API	**Vonprazan**

	manufacturer.	**Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Vonoprazan** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 12 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Aspirin** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cabpirin 100/10 Tablet **Manufacturer:** M/s Otsuka **Testing parameters:** Innovator Specifications **Batch #** 521559
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	Vonprazan Name: M/s AMI Life Sciences Address: Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. Aspirin Name: M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. Address: Yuquan Road, Huayin City, Shanxi Province, China.

API Lot No.	Vonoprazan fumarate		Aspirin
	Not provided		Not provided
Description of Pack (Container closure system)	30 in ALU-ALU Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 100 kg **Invoice #** 2122/SL/032 **Dated:** 05-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Decision of 333rd meeting of DRB

Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit evidence for GMP compliance status of Wallace Pharma.	Submitted
1.6.5	• Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.	Submitted
3.2.P.2	• Please justify that why drug coating method of tablet has been chosen instead of bilayer tablets which is a recommended method for tablet formulation for combination of two incompatible APIs?.	As one salt is enteric coated and other is immediate release so we chose drug coating method. The same formulation has been already approved by DRB.

	• Since Vonoprazan has a bitter taste, what steps have been taken to mask the bitter taste of API coating?	The formulation is in tablet dosage form and the dual coating will prevent the bitter taste
	• Please clarify whether in process test for Vonoprazan containing drug coating suspension has been performed? If yes, then submit validation data as well as anaylytical testing parameters with reference of testing.	Report submitted
	• Please submit data regarding weight gain of enteric coated tablet of Aspirin before and after spraying the drug coating suspension containing Vonoprazan.	Master formulation along with weight gains at each step Submitted
	• Please submit detailed procedure regarding disintegration time requirement for drug coating of vonoprazan and then disintegrating time of enteric coated aspirin.	Automatic exhaust system in lab scale coating pan
	• Please submit documented evidence that the coating machine used for drug coating suspension contains Human machine interface (HMI) to control the opening and closing of the exhaust during coating time.	Submitted
3.2.P.5	• Please submit detailed dissolution procedure along with reference.	Submitted

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1608.	**Import Molecules *(deferred in 333rd meeting of the DRB)***	
	Name, address of Applicant / Importer	**M/s Highsea Pharmaceutica** **Address: 2nd floor, 39 Commercial, Cavalry Ground, Lahore Cantt., Pakistan.**
	Details of Drug Sale License of importer	License No: 05-352-0058-100282D Address: 2nd foor, 39 Commercial, Cavalry Ground, Lahore Cantt, Pakistan. Address of Godown: NA Validity: 01.12.2027 Status: VALID
	Name and address of marketing authorization holder (abroad)	FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD. Address: No. 15, Zone D, Ming Xi County, Fujian. China.
	Name, address of manufacturer(s)	FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD. Address: No. 15, Zone D, Ming Xi County, Fujian. China.
	Name of exporting country	China.

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Photocopy submitted by firm** **Date of Legalization:** not provided • **CoPP:** Firm has submitted photocopy of CoPP certificate (No.20220009) dated 16-06-202 issued by Fujian Medical Products Administration, China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 15-06-2024 • **GMP:** The firm has also submitted photocopy of Drug Production License (duplicate) issued by Fujian Province Medical Products Administration.
	Details of letter of authorization / sole agency agreement	The agency agreement submitted doesn't mention anything regarding sole agency agreement or authorization / declaration of applicant in Pakistan to process for registration of drug product in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 37508 Dated: 22nd December 2023
	Details of fee submitted	PKR 150000/-: 27th September 2023 Slip # 3281403637
	The proposed proprietary name / brand name	**Seaflourane 250 ml Liquid for inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml contains Sevoflurane ……..... 100% w/v
	Pharmaceutical form of applied drug	Volatile Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anesthetic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	250ml per bottle
	Proposed unit price	PKR 29950 per 250 ml bottle
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Product name:** Sevoflo Solution **Importer:** Allmed (Pvt.) Ltd **Reg. #** 114071
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD.** Address: No. 15, Zone D, Ming Xi County, Fujian. **China.**
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C / RH 75% ± 5% for 06 months. **Real time:** 25ºC ± 2°C / RH 65% ± 5% for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Sevofurane Solution for inhalation **Manufacturer**: Maruishi Pharmaceutical Co. Ltd. Japan.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Brown Soda Lime glass bottle with aluminum cap lined with LDPE.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 09 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 65% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 65% ± 5%.

Evaluation by PEC:

During initial scrutiny, following observations / shortcomings were observed:

Section	Observations	Status

1.3.4	• Please submit legalized GMP certificate and Certificate of Pharmaceutical product.	Submitted
	• Please submit letter of authorization issued by Manufacturer abroad declaring Highsea Pharmaceutica Lahore as a sole distributor for the drug products mentioned in it.	Submitted
3.2.P.8	• Please submit complete stability data for long term storage conditions as per climatic conditions of Pakistan for the claimed shelf life of drug product.	Submitted

Decision: Approved as per Policy for inspection of Manufacturer abroad. Registration Board further decided that registration letter will be issued after submission of following:

i. Valid, Legalized CoPP to I&V Section.

ii. Valid, letter of authorization.

1609.	**Contract Manufacturing *(deferred in 333rd DRB meeting)***	
	Contract Giver Name, address of Applicant / Marketing Authorization Holder	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt.) Ltd. 19-km, Sheikhupura Road, Faisalabad. (DML # 000016)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4214 (dated: 14-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 10-01-2023 (Invoice # 0583698163)
	The proposed proprietary name / brand name	Flutinase Nasal Spray
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each actuation delivers: 100 mg suspension containing Fluticasone Propionate ……50 mcg
	Pharmaceutical form of applied drug	Nasal spray
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1's (60 metered sprays)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Ticovate *(Reg. # 060353)* **Manufacturer:** M/s Saffron
	Section Approval Letter from	Not provided

	Licensing Division of DRAP	
	GMP status of the Finished product manufacturer	**Acceptor:** GMP Certificate validity 02-01-2024. **Giver:** GMP Certificate validity 08-09-2024.
	Name and address of API manufacturer.	**Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. **GMP validity :** 06-09-2025.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Real time:** 30°C ± 2°C / 75% ± 5%RH for 60 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Flixonase Nasal Spray **Manufacturer:** M/s GSK **Testing parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China.
API Lot No.	AF-B200701, AF-B-210503
Description of Pack (Container closure system)	Spray will be filled in amber colored spray bottle with actuator, packed din card board carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	B # 052	B # 053	B # 054
Batch Size	200 kg	200 kg	200 kg
Manufacturing Date	11-2021	01-2022	12-2021
Date of Initiation	19-11-2021	26-02-2022	15-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** 18885/2020-DRAP **Dated:** 24-12-2020 **Quantity:** 1.5 kg **Invoice #** 14797/2021-DRAP **Dated:** 05-10-2021 **Quantity:** 1.5 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Decision of 333rd meeting of DRB: Deferred for confirmation of required manufacturing facility / section approval from Licensing Division.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit Section approval letter for **Topical Spray (Steroid) Section** of Saffron Pharma approved in meeting of Central Licensing Board.	Firm has submitted copy of letter for renewal of DML dated 16-05-2024. The letter specifies regularization of Nasal Spray Section (Steroidal) - Regularization

Decision: approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1610.	**Contract Manufacturing *(Case deferred in 333rd meeting of DRB)***	
	Contract Giver Name, address of Applicant / Marketing Authorization Holder	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284) Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt.) Ltd. 19-km, Sheikhupura Road, Faisalabad. (DML # 000016)**
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6361 (dated: 06-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 07-02-2023 (Invoice # 7466481766)
	The proposed proprietary name / brand name	Azeflu Plus Nasal Spray 137mcg + 50 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Spray / actuation (0.14gm) contains: Azelastine …… 137 mcg Fluticasone Propionate …… 50 mcg
	Pharmaceutical form of applied drug	Nasal spray in amber glass plastic bottle containing 120 metered sprays (23gm per bottle filling)
	Pharmacotherapeutic Group of (API)	Corticosteroid / anti-allergic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	25ml Amber glass plastic bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved **Dymista®**
	For generic drugs (me-too status)	N/A
	Section Approval Letter from Licensing Division of DRAP	Firm has submitted copy of letter for renewal of DML dated 16-05-2024. The letter specifies regularization of Nasal Spray Section (Steroidal) - Regularization
	GMP status of the Finished product manufacturer	**Acceptor:** GMP Certificate validity 02-01-2024. **Giver:** GMP Certificate validity 13-01-2024.
	Name and address of API manufacturer.	**Fluticasone Propionate** **Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. **GMP validity:** 06-09-2025. **Azelastine** **Name:** M/s Curia Italy SRL **Address**: Via Volturno, 41/43 (entrata principale)- Via Volturno, 45/48 (Entrata secondria)-20089 Rozzano (MI), Italy. **GMP validity :** valid
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Fluticasone propionate** Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months **Azelastine** Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Dymista Nasal Spray **Manufacturer:** M/s Meda Pharmaceuticals Germany **Testing parameters:** In-House Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	Fluticasone Propionate Name: M/s Aurisco Pharmaceutical Co. Ltd. Address: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. GMP validity: 06-09-2025. Azelastine Name: M/s Curia Italy SRL Address: Via Volturno, 41/43 (entrata principale)- Via Volturno, 45/48 (Entrata secondria)-20089 Rozzano (MI), Italy. GMP validity : 15-09-2025
API Lot No.	Flucitasone: AF-B-210503 Azelastine HCl: IE2100299A
Description of Pack (Container closure system)	Amber colored Pastic spray bottle with white plastic spray (0.14g) / actuator, a blue clip lock and a transparent lid.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	T – 003	T – 004	T – 005
Batch Size	200 kg	200 kg	200 kg
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	18-03-2022	18-03-2022	18-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Flucastine** **Dated:** 05-10-2021 **Quantity:** 1.5 kg **Azelastine** **Dated:** 50 grams **Quantity:** 29-11-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

"Decision in 333rd DRB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months."

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit Section approval letter for **Topical Spray (Steroid) Section** of Saffron Pharma approved in meeting of Central Licensing Board.	Submitted
1.6.5	• Please submit GMP certificate of API manufacturer of Azelastine HCl issued by regulatory authority of country of origin and should be inforce till date.	Submitted
3.2.P.7	• Please mention the exact pack size / presentation and number of actuation per container both in ml and grams.	120 metered sprays
	• Please submit data and documentation to support the initial priming (6 actuations) and repriming (at least one actuation) as stated in the labels and Product Information (PI).	Submitted
3.2.P.8	• Has firm performed investigation on the particle size distribution of the suspended particles for both actives in the formulation of the drug product?	Data submitted
	• Please justify that why Delivered Dose Uniformity, Particle Size Distribution and Droplet Size Distribution for effective dose delivery to the nasal cavity have not been included in the finished product specifications while it is part of the innovator's specifications?	Batch analysis report contains all tests as mentioned.
	• Please submit supportive data regarding in use stability of opened product.	Submitted
	• Please submit DRAP clearance documents for procurement of both APIs.	Submitted

Decision: approved with innovator specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1611.	**Contract manufacturing *(Deferred in 331st meeting)***	
	<u>Contract Giver</u> Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals Pvt. Ltd. (DML # 0008874) 30-km, Lahore-Sargodha Road, Sargodha.**
Contract Acceptor Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals **(DML # 000863)** Plot No. 527, Sunder Industrial Estate, Lahore.	
Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)	
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales	
Dy. No. and date of submission	Dy. No. 25072 (dated: 05-09-2022)	
Details of fee submitted	PKR 75,000/-: dated: 18-05-2022 (Invoice # 140345246004)	
The proposed proprietary name / brand name	**Dairo Sachet 2G**	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Strontium Ranelate ……2 g	
Pharmaceutical form of applied drug	Oral powder for reconstitution	
Pharmacotherapeutic Group of (API)	Anti-osteoporotic agent	
Reference to Finished product specifications	Innovator Specification	
Proposed Pack size	As per SRO	
Proposed unit price	As per SRO	
The status in reference regulatory authorities	EMEA approved formulation	
For generic drugs (me-too status)	Onita® for M/s PharmEvo	
GMP status of the Finished product manufacturer	**GMP certificate valid up to 13-02-2021**	
Name and address of API manufacturer.	**Name:** M/s CadChem Laboratories Limited. **Address:** 1060 Industrial Area, Phase-II, Chandigarh, India. **GMP Validity:** *Certificate not submitted*	
Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.	
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general	

	properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	**Stability study conditions**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	**Name:** Protelos 2g **Manufacturer:** Les Laboratories Servier France. **Testing parameters:** Innovator specifications
Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s CadChem Laboratories Limited. **Address:** 1060 Industrial Area, Phase-II, Chandigarh, India.		
API Lot No.	SROD04210013		
Description of Pack (Container closure system)	Filled in Sealed printed foil sachet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21G623	21K632	21L633
Batch Size	14000 sachet	14000 sachet	14000 sachet
Manufacturing Date	11/2021	11/2021	11/2021
Date of Initiation	19-11-2021	19-11-2021	19-11-2021
No. of Batches	03		

Administrative Portion

i.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** CLL/EXP/21-22/23 **Dated:** 05-10-2021 **Quantity:** 100kg

iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	For the manufacturing unit intended for contract manufacturing, please submit latest inspection report conducted within last three years or a valid GMP certificate which should be in force till date.	Submitted GMP validity: 24-11-2024
1.6.5	Please submit GMP certificate of API supplier which should be in force till date.	Submitted

Decision of 331st DRB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Decision: approved with innovator specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 09: Cases of drug products containing "Ketamine"

The following two cases were presented in 333rd meeting of Reg. Board and decided as mentioned at the end of cases:

1612.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Private Limited. 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. (DML # 000150)**
	Name, address of Manufacturing site.	**M/s Jawa Pharmaceuticals Private Limited. 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. (DML # 000150)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17599 (dated: 16-06-2022)
	Details of fee submitted	PKR 30,000/-: dated: 02-12-2021 (Invoice # 83478848)
	The proposed proprietary name / brand name	Ketarol Injection 50mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketamine (as HCl) …… 50 mg (100mg/2ml)
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	General Anesthesia

	Reference to Finished product specifications	USP Specification
	Proposed Pack size	05 ampoules of 2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Ketasol by M/s Indus Pharma
	GMP status of the Finished product manufacturer	Firm submitted inspection report dated 02-02-2023 GMP compliance "A" Liquid Sterile Injection (Psychotropic) Section. Liquid Injectable ampoule (psychotropic) section was granted by 30-05-2022 vide Letter No F. 1-38-91-Lic (Vol-II)
	Name and address of API manufacturer.	Ketamine HCl M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. GMP Certificate valid till 23-11-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e Ketaral injection by M/s Par Pharmaceuticals by performing quality tests (appearance, identification, pH , Assay & sterility test).

	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	Ketamine HCl M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. GMP Certificate valid till 23-11-2024		
API Lot No.	SLL/KH/0619026		
Description of Pack (Container closure system)	Clear colorless and sterile solution for injection is supplied in USP type I 2ml clear amber glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	20000 ampoules	20000 ampoules	20000 ampoules
Manufacturing Date	02/2021	02/2021	02/2021
Date of Initiation	17/05/2021	17/05/2021	17/05/2021
No. of Batches	03		

Administrative Portion

i.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	Ref. # 13452/2021/DRAP-AD-VI (I & E) **Dated** 20-01-2021 **Quantity:** 3000 gm
iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Decision of 330th meeting of DRB:
Registration Board deferred the case for opinion of Division of Control Drugs, DRAP regarding:

i. Legal status for API (Ketamine HCl) imported before declaration as controlled drug and afterwards its consumption by Drug Product Manufacturer for Pharmaceutical Development & stability batches. *ii. Requirement of manufacturing area whether segregated Psychotropic facility required or not*.
Remarks of the Evaluator: • The firm has imported the ketamine API (03 kg) as per provided invoice, for production of three (03) trial batches on 20th January 2021. Trial batches were manufactured in 02/2021. • Ketamine and its salts have been declared as "Psychotropic" vide SRO No. 1350(I)/2021 dated 15-10-2021. • Liquid Injectable ampoule (psychotropic) section was granted by 30-05-2022 vide Letter No F. 1-38-91-Lic (Vol-II). • Trial batch sizes needs clarification from firm.
Decision of 333rd meeting of DRB: Deferred for following: • **Justify that 03 kgs of API is sufficient for the manufacturing of 03 batches of 20000 ampoules each** • **Submission of BMRs for the said manufactured batches.** • **Submission of No Objection Certificate from Ministry of Narcotics Control**

1613.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Brookes Pharma Private Limited.** **58-59 Sector 15, Korangi Industrial Area, Karachi** **(DML # 000275)**
	Name, address of Manufacturing site.	M/s Brookes Pharma Private Limited. 58-59 Sector 15, Korangi Industrial Area, Karachi **(DML # 000275)**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 10005 (dated: 13-04-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 814271949980)
	The proposed proprietary name / brand name	**Ketaflex Injection 50mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketamine (as HCl) …… 50 mg
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	General Anesthesia
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	05 ampoules of 2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Ketasol by M/s Indus Pharma
	GMP status of the Finished product manufacturer	Central Licensing Board in its 277th meeting approved the renewal of DML including Injectable (Psychotropic) section.
	Name and address of API manufacturer.	**Ketamine HCl** M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C

		Taluka – khed, District – Ratnagiri, Maharashtra, India. **GMP Certificate valid till 23-11-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e Ketasol injection by M/s Indus** by performing quality tests (appearance, identification, pH , Assay & sterility test).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Ketamine HCl** M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. **GMP Certificate valid till 23-11-2024**
API Lot No.	SLL/KH/0618040
Description of Pack (Container closure system)	2ml amber glass USP type I ampoule, further packed in unit pack containing 05 ampoules with PVC tray and insert.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 24 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**PD-T-010E1**	**PD-PS-OO4A1**	**PD-T-O43KO**
Batch Size	5.0 Litre	10 Litre	5.0 Litre
Manufacturing Date	06/2021	01/2021	11/2020
Date of Initiation	02/06/2021	18/01/2021	02/12/2020
No. of Batches	03		

Administrative Portion		
i.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # SLL/E/18-19/868 Dated 6/11/2018 Quantity : 3 kg
iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Observations	**Reply**
3.2.P.2.3 Please justify that why Pharmaceutical equivalence studies have been performed against a local brand **Ketasol** instead of Innovator brand	Ketasol has been chosen because it is a registered brand in Pakistan by DRAP. This was also supported by "WHO Annexure 8 ; guidance for the selection of comparator pharmaceutical product for equivalence assessment of interchangeable multisource"
Please submit COA and approval documents of API import from DRAP for API LOT# SLL/KH/0618040.	Submitted

Decision of 330th meeting of DRB:

Registration Board deferred the case for opinion of Division of Control Drugs, DRAP regarding:

i. Legal status for API (Ketamine HCl) imported before declaration as controlled drug and afterwards its consumption by Drug Product Manufacturer for Pharmaceutical Development & stability batches.

ii. Requirement of manufacturing area whether segregated Psychotropic facility required or not.

Remarks of the Evaluator:

- The firm has imported the ketamine API (03kg) as per provided invoice vide Invoice # SLL/E/18-19/868 Dated 6/11/2018
- Trial batches were manufactured in 11/2020, 01/2021 & 06/2021.
- Ketamine and its salts have been declared as "Psychotropic" vide SRO No. 1350(I)/2021 dated 15-10-2021.
- Firm possess Liquid Injectable (psychotropic) section.
- Firm already possess registration of ketamine in 10 ml ampoule.

Decision of 333rd meeting of DRB: Approved subject to submission of No Objection Certificate issued by Ministry of Narcotics Control

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Brief History of the case:

The case was considered by the Authority in its 181st meeting. Openion of concerned Divisons and decision of Authority is narrated below:

Controlled Drugs Division:

The comments from the CD Division are as under:

"Reference Para 64/N, as discussed, it is submitted that Ketamine was included in the list of Controlled Drugs/substances in the year 2022 through S.R.O. 1350(I)/2021 dated 15th October 2021. Afterwards, the Pharmaceutical firms have been allocated quota of Ketamine HCl by the CAQCS.

Before the promulgation of the SRO, the matter regarding import and export of ketamine and ketamine containing Pharmaceutical Products was dealt by the QA&LT, Division, DRAP.

Moreover, the matter regarding requirement of segregated Psychotropic facility/section is a policy matter and pertains to the Licensing Division, DRAP."

The case was forwarded to the Licensing Division of DRAP for comments.

Division of Licensing DRAP:

The Comments from the Division of Licensing DRAP are as follows:

"Reference pre-paras it is submitted that the PE&R Division may proceed in the light of the decision by the DRAP Authority taken in its 73rd meeting as reproduced below:

The condition of dedicated section / facility for manufacturing of Ketamine shall not be applicable until declaration of Ketamine as a controlled substance by INCB."

Controlled Drugs Division

In exercise of its power conferred by the Control of Narcotic Substances Act, 1997, the Federal Government has declared Ketamine and its salts as Psychotropic substances. Copy of the notification is attached. Statement given at para 92/N, being contrary to the fact and law, is withdrawn. The matter may be dealt accordingly.

The matter was referred to the Division of Legal Affairs for comments in order to finalize the subject matter.

Legal Affairs Division:

The comments of the Legal Affairs Division are reproduced as under:

"Reference para 64/N onward. The views are sought by the Registration Board on the following two queries:

1. Legal status for API (Ketamine HCl) imported before declaration as controlled drug and afterwards its consumption by Drug Product Manufacturer for Pharmaceutical Development & stability batches.
2. Requirement of manufacturing area whether segregated Psychotropic facility required or not."

In this regard, it is submitted that the Federal Government has declared Ketamine and its salts as a Psychotropic substance vide S.R.O. 1350(I)/2021 dated 15.10.2021. Hence, after such a declaration, its use by the drug product manufacturer for pharmaceutical development and stability batches shall be regulated at par with other Psychotropic substances. The Division may proceed with the case as per requirements of manufacturing area for such substances given in Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and the SOPs of the Central Licensing Board."

Decision of the Authority:

The Authority decided that the case be processed considering the opinion of Legal Affairs Division that the Federal Government has declared Ketamine and its salts as a Psychotropic substance vide S.R.O. 1350(I)/2021 dated 15.10.2021. Ketamine and its salts shall be regulated at par with other Psychotropic substances.

Decision: Registration Board decided to take opinion of the Licencing division regardimng the requirement of dedicated psychotropic inj section. in the light of legal opinion

Agenda of Assistant Director (PE&R) (Mr. Sarfraz)

Minutes of Evaluator PEC-XXV
Muhammad Sarfraz Nawaz

Deferred Cases

1614.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries

		Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 12th, 2024, 7:34 am
	Details of fee submitted	PKR 30,000/- Dated 19-12-2023 Challan No. 8734923126
	The proposed proprietary name / brand name	Alcipro Eye Drop 0.3%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin Hydrochloride as Ciprofloxacin 3mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Eye Drops Solution, A clear and Colourless to pale yellow Solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml Drop-Tainer LDPE bottle and plug with a polystyrene or polypropylene cap.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**CILOXAN** (USFDA Approved)
	For generic drugs (me-too status)	Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries (Reg.No. 015693)
	Name and address of API manufacturer.	Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China		
API Lot No.	ZCFX21-015		
Description of Pack (Container closure system)	Packed in 5 ml Drop-Tainer LDPE bottle and plug with a polystyrene or polypropylene cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-TB01ED	CP-TB02ED	CP-TB03ED
Batch Size	800 Bottles	800 Bottles	800 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	17-05-2023	17-05-2023	17-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice DC No. 00036/0922 dated 20-09-2022 for API Loan received from M/s Newton Health Care Pvt. Ltd Karachi.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Submit DRAP Clearance from M/s Newton Health Care Pvt. Ltd Karachi for requisite API.
Submit copy of GMP certificate from API manufacturer abroad.

Firm Reply:

Dear Sir

M/S Zenith Chemical Industries (Pvt) Ltd, is local Lahore based manufacturer. There is no any need of clearance required from DRAP, while we are enclosing the GMP Certificate of M/S Zenith Chemical Industries (Pvt) Ltd attached.

Remarks of Evaluator:

Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China	M/S Zenith Chemical Industries (Pvt) Ltd, Lahore Pakistan

Decision M-335:

Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm reply:

Firm submitted requisite information.

Decision: Approved

1615.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable Vial SVP(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable Vial SVP(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 1st, 2024, 6:05 pm
	Details of fee submitted	PKR 30,000/- Dated 02-12-2023 Challan No. 728155159519

	The proposed proprietary name / brand name	Alcipro Infusion 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Ciprofloxacin Lactate as Ciprofloxacin 200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Intravenous infusion
	Reference to Finished product specifications	USP
	Proposed Pack size	100ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 2 mg/ml Solution for Infusion (MHRA Approved)
	For generic drugs (me-too status)	Quinoflox Infusion (Reg. 048423) of M/s Bosch Pharmaceuticals Pvt. Limited.
	Name and address of API manufacturer.	Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Quinoflox Infusion (Reg. 048423) of M/s Bosch Pharmaceuticals Pvt. Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China		
API Lot No.	DK21-2111224		
Description of Pack (Container closure system)	100ml glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-TB 001	CP-TB 002	CP-TB 003
Batch Size	300 Bottles	300 Bottles	300 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	16-05-2023	16-05-2023	16-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has stated that API as loan received from Bosch Pharmaceutical Pvt. Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

i. In Form 5-F, you mentioned that the API was obtained as a loan from Bosch Pharmaceutical Pvt. Ltd. However, the attached receipt is from M/s Newton Health Care Pvt. Ltd. in Karachi. Provide clarification with supporting documents, and include DRAP clearance for the API importer.

ii. Submit copy of GMP certificate from API manufacturer abroad.

Firm Reply:

This is to inform you that in the CTD Dossier Alcipro Infusion 200mg/100ml, we received API as loan from Indus Pharmaceuticals (Pvt) Ltd. It is an extra page added during the scanning of dossier. We are enclosing the supporting documents of API attached.
As per Document (GMP copy) manufacturer of API is as under:
M/s Shangyu Jingxin Pharmaceutical Co., Ltd. No. 31 Weisan Road, Hangzhou Bay, Shangyu, Shangyu Economic and Technological Development Area, China.

Remarks of Evaluator:
Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China	M/s Shangyu Jingxin Pharmaceutical Co., Ltd. No. 31 Weisan Road, Hangzhou Bay, Shangyu, Shangyu Economic and Technological Development Area, China.

Decision M-335: The board deferred the case for the submission of short comings communicated.
Firm reply:
It is clarify that the manufacturer of drug substance is M/s Shangyu Jingxin Pharmaceutical Co., Ltd. We are enclosing the AD invoice , COA, GMP Certificate and loan letter.

Decision: Approved

1616.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable vial SVP(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable vial SVP(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	December 18th, 2023, 2:46 pm
	Details of fee submitted	PKR 30,000/- Dated 02-12-2023 Challan No. 5389981692
	The proposed proprietary name / brand name	Levoful Infusion 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains Levofloxacin as Hemihydrate.....500 mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Infusion
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	100ml vial
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Levofloxacin 5mg/ml solution for infusion (MHRA Approved)
	For generic drugs (me-too status)	Leflox Infusion of M/s Getz Pharma Pvt. Ltd. (Reg.No. 024664)
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Leflox Infusion of M/s Getz Pharma Pvt. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China
API Lot No.	DK21-2111224
Description of Pack (Container closure system)	100ml glass vial
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LF-TB-001	LF-TB-002	LF-TB-003
Batch Size	30 L	30 L	30 L
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	02-06-2023	02-06-2023	02-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has inform that API received as loan from M/s Newton Health Care Pvt. Ltd. and submit DRAP clearance dated 07-07-2022 of said firm.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Analysis performed on HPLC system which is not CFR 21 compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Submit a copy of the GMP certificate from the API manufacturer abroad.

Why is product testing not performed using HPLC software 21CFR?

Firm Reply:

This to inform you that in CTD Dossier Levoful Infusion 500mg/100ml the statement against the point Compliance record of HPLC Software 21CFR & audit trail reports on product testing, the statement given The analysis performed was on using HPLC Software System which is not CFR 21 compliant. It is a typographical error made by us so for this mistake we apologize and request you to omit the word not. We are performing analysis on CFR 21 compliant system.

Remarks of Evaluator:

Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China	Zhejiang East-Asia Pharmaceutical Co., Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China Copy of GMP shows validity till 15-08-2021

Decision M-335: Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm submit reply:

It is clarify that the drug substance manufacturer is Zhejiang East-Asia Pharmaceutical Co., Ltd. We are enclosing the ADC, COA, GMP, and loan letter.

(Zhejiang East-Asia Pharmaceutical Co., Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China)

Decision: Approved

1617.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 29th, 2024, 10:39 am
	Details of fee submitted	PKR 30,000/- Dated Dec 19, 2023 4:33 PM Challan No. 8628547720
	The proposed proprietary name / brand name	Alvit Injection 1000mcg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contain: Vitamin B12 .....1000mcg
	Pharmacotherapeutic Group of (API)	Vitamin ATC Code B03BA01
	Pharmaceutical form of applied drug	IV/IM Injection
	Reference to Finished product specifications	USP
	Proposed Pack size	Amber colour glass ampoule 1mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(PDMA Japan approved)
	For generic drugs (me-too status)	Vitamin B12 Injection of M/s Amrose Pharmaceutical (Reg.No. 026880)
	Name and address of API manufacturer.	M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China COA of DS from this. As per Module-2 Hebei Huarong Pharmaceutical Co., Ltd. East Road, North Circle, Shijiazhuang, Hebei, China Secondary ref. standard use from this. API Manufacturer as per Module 3 Sichuan Province Yuxin Pharmaceutical Co., Ltd No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (Southern District), Sichuan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis

		and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Cyanocobalmin Injection of M/a Amaan Pharma Lahore
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hebei Huarong Pharmaceutical Co., Ltd. East Road, North Circle, Shijiazhuang, Hebei, China Secondary ref. standard use from this.		
API Lot No.	C210806F		
Description of Pack (Container closure system)	Amber colour glass ampoule 1ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VT-TB-001	VT-TB-002	VT-TB-003
Batch Size	3000 Ampoule	3000 Ampoule	3000 Ampoule
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	15-05-2023	15-05-2023	15-05-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	API received as loan from M/s Ahsons Drug Company Tando Adam firm submitted copy of Drud Import License No. K-1490452716974 API manufacturer M/s M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API received as loan from M/s Ahsons Drug Company Tando Adam firm submitted copy of Drud Import License No. K-1490452716974 API manufacturer M/s M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	As per USP Monograph analysis was performed using UV Spectrophotometer.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Shortcomings/Clarification	**Firm response**
Module 1 states that the API manufacturer is M/s Yuxing Bio-Technology (Group) Co., Ltd., located in Xicheng District, Ningjin County, Xing Tai City, Hebei Province, China. The Certificate of Analysis (COA) for the Drug Substance (DS) is obtained from this manufacturer. According to Module 2, the API manufacturer is M/s Hebei Huarong Pharmaceutical Co., Ltd., situated on East Road, North Circle, Shijiazhuang, Hebei, China, and the secondary reference standard is sourced from this manufacturer. In Module 3, the API manufacturer is M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., located at No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (Southern District), Sichuan. You are advised to clarification with supporting documents regarding the API manufacturer used for product development.	This is to inform you that the API Manufacturer of Vitamin B12 (Cyanocobalamin) is M/s. Yuxing Biotechnology (Group) Co. Ltd. The certificate of analysis COA for the Drug Substance is also same as M/s. Yuxing Biotechnology (Group) Co. Ltd. The drug product manufactured from same manufacturer M/s. Yuxing Biotechnology (Group) Co. Ltd. We are enclosing the supporting documents also.
The stability data for batch no. VT-TB-001 indicates an initiation date of 15-05-2023, but within the same dataset, the initiation date is mentioned as 12-05-2023. Similarly, for Batch no. VT-TB-002, the initiation date is stated as 15-05-2023, while in the table, it is documented as 13-05-2023. Please provide clarification on this discrepancy.	The stability data for batch No. VT-TB-001 indicates an initiation date of 15/05/2023 while the 12/05/2023 is the analysis date of batch No. VT-TB-001, Similarly batch No. VT-TB-002 indicates an initiation date of 15/05/2023 while the 13/05/2023 is the analysis date of batch No. VT-TB-002.

Decision M-335:
The board deferred for submission of following:

1. Details of drug substance manufacturer along with evidence of procurement attested by AD I&E DRAP.
2. Clarification regarding dates of manufacturing and initial analysis of batch release of stability trial batches along with relevant manufacturing and analytical record.

Firm Reply:
(i)This is to inform you that the API Manufacturer of Vitamin B12 (Cyanocobalamin) is M/s. Yuxing Biotechnology (Group) Co. Ltd. The certificate of analysis COA for the Drug Substance is also same as M/s. Yuxing Biotechnology (Group) Co. Ltd. The drug product manufactured from same manufacturer M/s. Yuxing Biotechnology (Group) Co. Ltd. We are enclosing the supporting documents also.
(ii)The stability data for batch No. VT-TB-001 indicates an initiation date of 15/05/2023 while the 12/05/2023 is the analysis date of batch No. VT-TB-001, Similarly batch No. VT-TB-002 indicates an initiation date of 15/05/2023 while the 13/05/2023 is the analysis date of batch No. VT-TB-002.

Decision: Approved

1618.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 18th, 2024, 2:21 pm
	Details of fee submitted	PKR 30,000/- Dated Dec 19, 2023 4:32 PM Challan No. 108672030604
	The proposed proprietary name / brand name	Almox Eye Drop 0.5%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Moxifloxacin Hydrochloride as Moxifloxacin 5mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Eye Drops, Solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Vigamox** (USFDA Approved)
	For generic drugs (me-too status)	Moxigan 0.5% Sterile Ophthalmic Solution Of M/s Barrett Hodgson Pakistan (Pvt) Ltd.,Karachi (Reg.No. 042111)

	Name and address of API manufacturer.	Module 1 M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Milan Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dist. Gandhinagar, Gujarat, India M-2 API Manufacturer: M/s Orex Pharma Pvt. Ltd. C/O Cureworth Drugs and intermedia tes pvt. Ltd. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Moxigan 0.5% Sterile Ophthalmic Solution of M/s Barrett Hodgson Pakistan (Pvt) Ltd.,Karachi (Reg.No. 042111)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	
API Lot No.	Mox 21103
Description of Pack (Container closure system)	Pale yellow to greenish colour clear solution filled in 5ml drop trainer LDPE Bottle plug with a polystyrene or polypropylene cap.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MOX-TB01ED	MOX-TB02ED	MOX-TB03ED
Batch Size	800 Bottles	800 Bottles	800 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	21-05-2023	21-05-2023	21-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has inform that API Loan received from M/s Newton Health Care Pvt. Ltd Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Shortcomings/Clarification	**Firm response**
Submit DRAP Clearance from M/s Newton Health Care Pvt. Ltd Karachi for requisite API.	Not submitted
Submit copy of valid GMP certificate from API manufacturer abroad.	Not submitted
Submit DS data from API used for DP	Not submitted

Remarks of Evaluator:
Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Module 1 M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Milan Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dist. Gandhinagar, Gujarat, India Module-2 API Manufacturer: M/s Orex Pharma Pvt. Ltd. C/O Cureworth Drugs and intermedia tes pvt. Ltd. India	M/S Zenith Chemical Industries (Pvt) Ltd, Lahore Pakistan

Decision M-335:
Deferred for submission of following:

1. Details of drug substance manufacturer along with evidence of procurement attested by AD I&E DRAP.
2. Copy of valid GMP certificate from API manufacturer abroad.

Firm reply: Firm submitted requisite documents.		
Decision: Approved		
1619.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt Ltd., Plot No. 3 26 km Lahore-Shariqpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jencholic 5mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 15704 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets USFDA approved
	Me-too status	Obliva 5mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JNC-PB-031001	JNC-PB-031002	JNC-PB-031003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	10-04-2020	10-04-2020	10-04-2020
No. of Batches	03		
Date of Submission	28-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**

1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Lansodex capsule 60mg and 30mg, Sofopas Tablet 400/90, for which the inspection was conducted on 10-12-2018, the report was presented in 287th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively. Batches:(201612001, 201612002, 201612003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. **Valid until May,05,2022**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CY119050 dated 29-11-2019 from exporter M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China, for import of 92.5g of Obeticholic acid (Batch No. JZ191101-1) in name of M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura attested by AD (I&E) DRAP Lahore dated 12-12-2019.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** JNC-PB-031001 / 1000 tablets / 04-2020 JNC-PB-031002 / 1000 tablets / 04-2020 JNC-PB-031003 / 1000 tablets / 04-2020
11.	Record of comparative dissolution data (where applicable)	Submitted Comparative dissolution was performed against Abeticholic tablet (5mg) Reg. No. 109521 (Batch No. DY001) of M/s Dyson Research Laboratories in 0.1N HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.

Decision M-333: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

Decision of M-333rd meeting of RB	**Firm reply**
Latest GMP inspection report conducted within period of 3 years	GMP inspection report submitted. Date of inspection 04-06-2022
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm submit copy of GMP from **Nantong chemical & Medical Industry Association** valid until 21-02-2026
6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.	CDP is performed on 12 unites for both test and reference product. It is performed in 2 stages, 6 unites are used in stage-1 and 6 unites are used in stage-2 for each dissolution medium. Data for 12 unites is submitted.

Decision: Approved

1620.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt Ltd., Plot No. 3 26 km Lahore-Shariqpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jencholic 10mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…10mg

	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 15705 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets USFDA approved
	Me-too status	Obliva 10mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JNC-PB-032001	JNC-PB-032002	JNC-PB-032003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	10-04-2020	10-04-2020	10-04-2020
No. of Batches	03		
Date of Submission	28-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Lansodex capsule 60mg and 30mg, Sofopas Tablet 400/90, for which the inspection was conducted on 10-12-2018, the report was presented in 287th meeting of Registration Board. The report confirms following points: □□The HPLC software is 21CFR compliant. □□Firm has demonstrated audit trail reports of testing.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively.
Batches:(201612001, 201612002, 201612003)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. Valid until May,05,2022</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. CY119050 dated 29-11-2019 from exporter M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China, for import of 92.5g of Obeticholic acid (Batch No. JZ191101-1) in name of M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura attested by AD (I&E) DRAP Lahore dated 12-12-2019.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JNC-PB-032001</td><td>1000 tablets</td><td>04-2020</td></tr>
<tr><td>JNC-PB-032002</td><td>1000 tablets</td><td>04-2020</td></tr>
<tr><td>JNC-PB-032003</td><td>1000 tablets</td><td>04-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted</td></tr>
</table>

		Comparative dissolution was performed against Abeticholic tablet (10mg) Reg. No. 109522 (Batch No. DZ001) of M/s Dyson Research Laboratories in 0.1N HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.

Decision M-333: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

Decision of M-333rd meeting of RB	**Firm reply**
Latest GMP inspection report conducted within period of 3 years	GMP inspection report submitted. Date of inspection 04-06-2022
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm submit copy of GMP from **Nantong chemical & Medical Industry Association** valid until 21-02-2026
6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.	CDP is performed on 12 unites for both test and reference product. It is performed in 2 stages, 6 unites are used in stage-1 and 6 unites are used in stage-2 for each dissolution medium. Data for 12 unites is submitted.

Decision: Approved

1621.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Cholimac 5mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16147 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO

	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets U.S (FDA) approved
	Me-too status	Obliva 5mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	CLT-PB-01	CLT-PB-02	CLT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	05-09-2020	05-09-2020	05-09-2020
No. of Batches	03		
Date of Submission	09-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Gencox 90mg Tablet, for which the inspection was conducted on 31-12-2020 and 11-01-2021, the report was presented in 312th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months

<table>
<tr><td></td><td></td><td>and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively.
Batches:(201612001, 201612002, 201612003)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. Valid until May,05,2022</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Not submitted</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>CLT-PB-01</td><td>900 tablets</td><td>08-2020</td></tr>
<tr><td>CLT-PB-02</td><td>900 tablets</td><td>08-2020</td></tr>
<tr><td>CLT-PB-03</td><td>900 tablets</td><td>08-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not Provided. The firm has requested to exempt the study of CDP as Innovator or competitor product is not available in Pakistan.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted except COAs of all time points.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Shortcomings:
Latest GMP inspection report conducted within period of 3 years.
Submit documents for the procurement of API with approval from DRAP.
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
Submit record of comparative dissolution data
Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.</td></tr>
<tr><td colspan="3">Decision M-333: Registration Board deferred the case for submission of reply to the above cited shortcomings.
Reply of the Firm:
<table>
<tr><th>Decision of M-333rd meeting of RB</th><th>Firm reply</th></tr>
</table></td></tr>
</table>

Latest GMP inspection report conducted within period of 3 years	GMP inspection report submitted, Inspection dated 04-06-2022
Submit documents for the procurement of API with approval from DRAP	Submitted documents issued by AD (I&E), Lahore dated 22-04-2018 along with invoices.
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm submit copy of GMP from **Nantong chemical & Medical Industry Association** valid until 21-02-2026
Submit record of comparative dissolution data	Submitted
Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.	Submitted

Decision: Approved

1622.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Cholimac 10mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…10mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16146 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets U.S (FDA) approved
	Me-too status	Obliva 10mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	CMT-PB-01	CMT-PB-02	CMT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	08-2020	08-2020	08-2020

Date of Initiation	07-09-2020	07-09-2020	07-09-2020
No. of Batches	03		
Date of Submission	09-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Gencox 90mg Tablet, for which the inspection was conducted on 31-12-2020 and 11-01-2021, the report was presented in 312th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively. Batches:(201612001, 201612002, 201612003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. **Valid until May,05,2022**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not submitted**
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** CMT-PB-01 / 900 tablets / 08-2020 CMT-PB-02 / 900 tablets / 08-2020 CMT-PB-03 / 900 tablets / 08-2020
11.	Record of comparative dissolution data (where applicable)	**Not Provided.** The firm has requested to exempt the study of CDP as Innovator or competitor product is not available in Pakistan.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted **except** COAs of all time points.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit documents for the procurement of API with approval from DRAP.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- Submit record of comparative dissolution data
- Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.

Decision M-333: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

Decision of M-333rd meeting of RB	**Firm reply**
Latest GMP inspection report conducted within period of 3 years	GMP inspection report submitted, Inspection dated 04-06-2022
Submit documents for the procurement of API with approval from DRAP	Submitted documents issued by AD (I&E), Lahore dated 22-04-2018 along with invoices.
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm submit copy of GMP from **Nantong chemical & Medical Industry Association** valid until 21-02-2026
Submit record of comparative dissolution data	Submitted
Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.	Submitted

Decision: Approved

1623.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.40560 dated 06-12-2018;Fee Rs: 20,000/- dated 05-12-2018

	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	-
	Remarks of the Evaluator [V]	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision of 295th meeting of RB:	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.		
API Lot No.	E-20190920-D02-E06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 1, 2, 3 (months) Real Time: 0, 3 (months)		
Batch No.	NJ-T1	NJ-T2	NJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	30-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# E-20190920-D02-E06-01) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Pharmasol (Pvt) Ltd, Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively.
Batches:(20160606, 20161017,20161219)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 28-09-2018 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Fuxin Food and Drug Administration, People’s Republic of China. Valid till 27-09-2020.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 20200219-U dated 19-02-2020 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd. No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Pharmasol (Pvt) Ltd, Lahore attested by AD (I&E) DRAP Lahore dated 05-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not provided</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>NJ-T1</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T2</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T</td><td>2500 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Jardiance tablet (10mg) Batch No. C11319 in 0.1N HCl, Acetate buffer (pH 4.0) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted (only for accelerated stability)</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Initially applied with brand name “Empazin” while submitted stability data with brand name “Empaken”.
Shortcomings:
• Latest GMP inspection report conducted within period of 3 years.</td></tr>
</table>

- Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.
- Justification for using overage in master formula.
- Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify.
- Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5?
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).
- Justification of performing 3rd point time test in January instead of December.

Decision 333:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

Shortcomings	**Response of the Firm**
Latest GMP inspection report conducted within period of 3 years.	GMP inspection report dated 19-08-2022 & 22-08-2022
Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.	Submitted
Provide reference of previous approval of applications with stability study data of the firm.	Onsite inspection was conducted on 04-09-2023 for cinacalcet (as HCL) 30mg and Dexlansoprazole 30mg & 60mg by constituted panel of DRAP
Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	Submitted
Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.	Online DML of API manufacturer from official website of NMPA China dated 14-02-2024 valid 2027-11-17, scope of production shows applied molecule.
Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.	Hydroxypropyl cellulose was not available at the time of the development of the Empagliflozin 10mg tablet therefore PVP was used as a binder. PVP is most widely used in tablet as a binder. There found no incompatibility with Empagliflozin and any other excipient used. Compatibility report submitted.
Justification for using overage in master formula.	The overage was using to compensate the process loss during the manufacturing process. As the geometrical mixing was used for the batch manufacturing and quality of the API is in small therefore overage was used. However the batch results and the 6th month accelerated 24 months real time stability data shows that the selected manufactured process and the formulation is robust and there is no need of the overage to compensate the process loss. Therefor we

	commit that the commercial batches will be manufactured without overage.
Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify	For dissolution parameters of empagliflozin 10mg USFDA Dissolution data base was consulted. In USFDA dissolution data base for the Empagliflozin they refer to FDA's Dissolution guidance, 2018, where 50rpm and 30minutes is recommended but we used 20minutes sampling time.
Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5?	It was a typographic mistake. Acetate buffer of pH 4.5 buffer was used for the CDP.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).	Submitted
Justification of performing 3rd point time test in January instead of December	Empazin 10mg 3rd time point stability study was due in Decemer 2020, the testing at the due time was missed inadvertently and then performed on January 2021. The stability was continued and tested as per the due time points till 6th months accelerated and 24 months real time.

Decision: Approved

1624.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy. No.40561 dated 06-12-2018;Fee Rs: 20,000/- dated 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	-
	Remarks of the Evaluator [V]	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision of 295th meeting of RB:	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.
API Lot No.	E-20190920-D02-E06-01

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 1, 2, 3 (months) Real Time: 0, 3 (months)		
Batch No.	OJ-T1	OJ-T2	OJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	30-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# E-20190920-D02-E06-01) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Pharmasol (Pvt) Ltd, Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25˚C ± 2˚C / 60% ± 5%RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606, 20161017,20161219)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 28-09-2018 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Fuxin Food and Drug Administration, People's Republic of China. Valid till 27-09-2020.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. 20200219-U dated 19-02-2020 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd. No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Pharmasol (Pvt) Ltd, Lahore attested by AD (I&E) DRAP Lahore dated 05-03-2020.

<table>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not provided</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>NJ-T1</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T2</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T</td><td>2500 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Jardiance tablet (10mg) Batch No. 906126 in 0.1N HCl, Acetate buffer (pH 4.0) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted (only for accelerated stability)</td></tr>
</table>

REMARKS OF EVALUATOR[X]

Initially applied with brand name "Empazin" while submitted stability data with brand name "Empaken".

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide stability study data of API from API manufacturer as per zone IV-A conditions. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the product for 6 months along with degradation studies in the finished pharmaceutical product.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.
- Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify.
- Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).
- Justification of performing 3rd point time test in January instead of December.

Decision 333: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

Shortcomings	Response of the Firm
Latest GMP inspection report conducted within period of 3 years.	GMP inspection report dated 19-08-2022 & 22-08-2022

Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.	Submitted
Provide reference of previous approval of applications with stability study data of the firm.	Onsite inspection was conducted on 04-09-2023 for cinacalcet (as HCL) 30mg and Dexlansoprazole 30mg & 60mg by constituted panel of DRAP
Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	Submitted
Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.	Online DML of API manufacturer from official website of NMPA China dated 14-02-2024 valid 2027-11-17, scope of production shows applied molecule.
Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.	Hydroxypropyl cellulose was not available at the time of the development of the Empagliflozin 10mg tablet therefore PVP was used as a binder. PVP is most widely used in tablet as a binder. There found no incompatibility with Empagliflozin and any other excipient used. Compatibility report submitted.
Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify	For dissolution parameters of empagliflozin 10mg USFDA Dissolution data base was consulted. In USFDA dissolution data base for the Empagliflozin they refer to FDA's Dissolution guidance, 2018, where 50rpm and 30minutes is recommended but we used 20minutes sampling time.
Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5?	It was a typographic mistake. Acetate buffer of pH 4.5 buffer was used for the CDP.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).	Submitted
Justification of performing 3rd point time test in January instead of December	Empazin 10mg 3rd time point stability study was due in Decemer 2020, the testing at the due time was missed inadvertently and then performed on January 2021. The stability was continued and tested as per the due time points till 6th months accelerated and 24 months' real time.

Decision: Approved

1625.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Empacor 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.28171 dated 17-08-2018; Fee Rs: 20,000/- dated 17-08-2018
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse

	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China		
API Lot No.	EPG20201001		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TEM-001	TEM-002	TEM-003
Batch Size	2500 tablets	2500 tablets	2300 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	16-03-2021	16-03-2021	16-03-2021
No. of Batches	03		
Date of Submission	07-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# EPG20201001) of API from M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China and M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 06 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, & 0, 1, 2, 3 & 6 months respectively. Batches:(Z1215-170601, Z1215-170602, Z1215-170603)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 31-03-2019 in the name of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China issued by Linhai Food

<table>
<tr><td></td><td></td><td>and Drug Association, People's Republic of China. Valid till 30-03-2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. HY201202-1 dated 21-12-2020, for import of 1.0 Kg of Empagliflozin in name of M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 18-01-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TEM-001</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEM-002</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEM-003</td><td>2500 tablets</td><td>03-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed in acidic buffer pH 1.2, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted except summary data sheets</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Initially applied with brand name "Glifloz" while submitted stability data with brand name "Empacor".
<u>Shortcomings:</u>
• Latest GMP inspection report conducted within period of 3 years.
• Provide reference of previous approval of applications with stability study data of the firm.
• Specify comparator brand against which comparative dissolution has been performed.
• Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).</td></tr>
<tr><td colspan="3">Decision 333:
Registration Board deferred the case for submission of reply to the above cited shortcomings.
Firm Reply:
<table>
<tr><th>Deficiencies as per Board decision</th><th>Response of the Firm</th></tr>
<tr><td>Latest GMP inspection report conducted within period of 3 years</td><td>Copy of GMP dated 14-11-2023.</td></tr>
<tr><td>Provide reference of previous approval of applications with stability study data of the firm.</td><td>Previously product inspection was not done</td></tr>
<tr><td>Specify comparator brand against which comparative dissolution has been performed</td><td>Declared that due to unavailability of innovator pack CDP was done against the comparator Brand of Empaa 10mg Tablet of M/s Weather folds Pharmaceutical</td></tr>
</table></td></tr>
</table>

Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).	Submitted

Decision: Approved

1626.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Empacor 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy. No.28172 dated 17-08-2018; Fee Rs: 20,000/- dated 17-08-2018
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China		
API Lot No.	EPG20201001		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TEG-001	TEG-002	TEG-003
Batch Size	2500 tablets	2500 tablets	2300 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	18-03-2021	18-03-2021	18-03-2021
No. of Batches	03		
Date of Submission	07-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch# EPG20201001) of API from M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China and M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 06 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, & 0, 1, 2, 3 & 6 months respectively.
Batches:(Z1215-170601, Z1215-170602, Z1215-170603)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 31-03-2019 in the name of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China issued by Linhai Food and Drug Association, People’s Republic of China. Valid till 30-03-2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. HY201202-1 dated 21-12-2020, for import of 1.0 Kg of Empagliflozin in name of M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 18-01-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TEG-001</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEG -002</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEG -003</td><td>2500 tablets</td><td>03-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed in acidic buffer pH 1.2, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
</table>

REMARKS OF EVALUATOR[X]

Initially applied with brand name "Glifloz" while submitted stability data with brand name "Empacor".

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Specify comparator brand against which comparative dissolution has been performed.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

Decision 333:

Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm Reply:

Deficiencies as per Board decision	**Response of the Firm**
Latest GMP inspection report conducted within period of 3 years	Copy of GMP dated 14-11-2023.
Provide reference of previous approval of applications with stability study data of the firm.	Previously product inspection was not done
Specify comparator brand against which comparative dissolution has been performed	Declared that due to unavailability of innovator pack CDP was done against the comparator Brand of Empaa 10mg Tablet of M/s Weather folds Pharmaceutical
Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).	Submitted

Decision: Approved

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

b. Deferred Cases

1627.	Name and address of manufacturer /Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore. "**
	Brand Name +Dosage Form + Strength	Phosvit Injection 10ml
	Composition	Each ml contains: Butaphosphan…….100mg Cyanocobalamin……0.05mg
	Diary No. Date of R& I & fee	Dy.No. 26449 dated 01-08-2018 Rs.20,000/- Dated 01-08-2018
	Pharmacological Group	Phosphorus/Supplement/Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10ml / Decontrolled
	Me-too status	Not found in 10ml
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name of firm	
	Decision M-295: Deferred for evidence of applied formulation/drug already approved by DRAP ((generic / me-too status) along with registration number, brand name of firm. Firm Reply: The firm had already been granted registration of Phosvit Injection in 50ml (Reg.# 088081 & Phosvit Injection 100ml Reg.# 099371).	

	Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
1628.	Name and address of manufacturer /Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Sterivit Injection 10ml.
	Composition	Each ml Contains: DL-Acetyl methionine ……200mg Cyanocobalamin ……0.2mg L-Carnitine HCl 61.3mg Eq. To L-Carnitine 50mg Alpha-Tocopherol Acetate 32.9mg Eq. To Alpha-Tcopherol ……..…30mg
	Diary No. Date of R& I & fee	Dy. No 26577 dated 09-10-2020; Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Vitamin & amino acid.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	Decontrolled.
	Me-too status	Metabolase Forte Injectable Solution (50, 100, 250ml), Imported by Prix pharma from Italy, Reg. No. 043109.
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator. Evidence of applied formulation/drug already approved by DRAP in applied fill volume (generic / me-too status) along with registration number, brand name and name of firm.	
	Decision M-312: Deferred for evidence of applied formulation/drug already approved by DRAP in applied fill volume (generic / me-too status) along with registration number, brand name and name of firm Firm Reply: The firm had already been granted registration of Sterivit Injection 50ml (Reg.#109968) & Sterivit Injection 100ml (Reg.# 095650) & Sterivit Injection 250ml (Reg.#109969). **Decision: Approved**	

1629.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fartylo Fos Oral Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Fosfomycin Calcium…200mg Fructose…180mg Magnesium Sulphate…100mg Sodium Phosphate…150mg
	Diary No. Date of R& I & fee	Dy.No 14646 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 150157930)
	Pharmacological Group	Antibiotic/ Antibacterial/ Minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:**

		• Role of sodium chloride in instant formulation • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Decision of 330th meeting of RB	**Firm Reply**
Role of sodium chloride in instant formulation	The role of Sodium Chloride in instant formulation is just the volume makeup.
Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Submitted Rs. 30,000/- Slip no.# 9487928511 dated Sep 20, 2023

Decision: Approved

1630.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Endclo Plus Suspension
	Composition	Each ml contains: Closantal…110mg
	Diary No. Date of R& I & fee	Dy.No 8506 dated 01-04-2022 Rs.30,000/- dated 28-03-2022 (slip No.3413491102)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml, 5000ml; Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. **Shortcomings:** • Clarification regarding the applied formulation is required since Closantal…**110gm/100ml** is mentioned in cover letter and throughout the dossier while Closantal…**110gm/1000ml** is mentioned in label claim in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision M-331: Deferred for following: • clarification regarding the applied formulation since Closantal…110gm/100ml is mentioned in cover letter and throughout the dossier while Closantal…110gm/1000ml is mentioned in label claim in Form-5 • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. **Firm reply:** Correct composition is as per form-5 while composition mentioned in cover letter is typo error. Generic drug is Closafs-11% Liquid (Reg. 058754) Composition as per generic is as under: Each ml contains: Closantal…110mg	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1631.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Curafluke Drench

	Composition	Each ml contains: Fenbendazole…50mg Refoxanide…50mg
	Diary No. Date of R& I & fee	Dy.No 8510 dated 01-04-2022 Rs.30,000/- dated 28-03-2022 (slip No.3071158844)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml, 5000ml; Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. **Shortcomings:** • Clarification regarding the applied formulation is required since "Fenbendazole…5gm, Refoxanide…5gm **per ml**" is mentioned in cover letter while "Fenbendazole…5gm, Refoxanide…5gm **per 100ml**" is mentioned in label claim in Form-5 and throughout the dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision M-331: Deferred for the following: • Clarification regarding the applied formulation since "Fenbendazole…5gm, Refoxanide…5gm per ml" is mentioned in cover letter while "Fenbendazole…5gm, Refoxanide…5gm per 100ml" is mentioned in label claim in Form-5 and throughout the dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply:** Correct composition is as per form-5 while composition mentioned in cover letter is typo error. Generic drug is Fasifen Oral Drench (Reg. 057065) Composition as per generic is as under: Each 100ml contains: Fenbendazole…5gm Refoxanide…5g	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		

1632.

Manufacture	**Brand Name & Composition** **Pharmacological Group**	**Type of Form** **Initial date, diary** **Fee including differential fee** **Demanded Price / Pack size**	**International status in stringent regulatory agencies**
M/s Zakfas Pharmaceuticals (Pvt) Ltd, 12-Km, Bosan Road, Multan	Rectin-D.S Injection Each ml contains:- Ivermectin….12mg Anthelmintic	Form 5 23-06-2011 diary # 188 Rs.8000 R&I & Rs.12000 vide diary # 79 dated 11-09-2013 Decontrolled /10ml, 30ml, 50ml, 100ml, 500ml,	Require to be verified

Decision of 254th Meeting of RB:
Deferred for
- Finished product specifications are not provided.
- Calculations in salt and base are not provided.
- Last inspection report conducted within period of 1 year is not provided.

- Commitment as per the decision of Board is not provided.
- Outline method of manufacture is not provided.
- Complete description of formulation is not provided.
- The firm has submitted single page stability data without any supporting documents.
- Formulation requires justifications as no buffering agents are added to stabilize the formulation.
- Only one volume requires to be applied per application as per the decision of Board.

Deficiencies as per RB Decision 254	**Firm Reply**
Finished product specifications are not provided.	BP
Calculations in salt and base are not provided	Submitted
Last inspection report conducted within period of 1 year is not provided	DML renewal Recommended report Inspection dated 15-06-2021
Commitment as per the decision of Board is not provided	Submitted
Outline method of manufacture is not provided	Submitted
Complete description of formulation is not provided	Submitted
The firm has submitted single page stability data without any supporting documents	For local manufacturer as per form-5 stability data is not required
Formulation requires justifications as no buffering agents are added to stabilize the formulation	Submitted
Only one volume requires to be applied per application as per the decision of Board	50ml

Remarks of evaluator:

Generic status is not confirmed

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied pack size alongwith registration number, brand name and name of firm

1633.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Oxycloz Plus Drench
	Composition	Each gram contains: Oxfendazole……62.50mg Oxyclozanide……..22.65mg Cobalt Sulphate……1.67mg Sodium Selenite……0.50mg
	Diary No. Date of R & I & fee	Dy.No.442 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status	Punch Drench of M/s Selmore Pharma (Pvt) Ltd., Lahore 032206 if each 100ml contains is applied.
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	• Applied as drench while gm/ mg is applied in composition.
	Decision of 296th meeting of Registration Board:	Deferred for following reasons: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

		• Formulation is applied as drench while gm/ mg is applied in composition.
	Submission of the firm:	Firm has revised their label claim with submission of 5000/- vide deposit slip No. 2030994 dated 01-04-2021 from Each gram contains to Each ml contain. They also provided Punch Drench of M/s Selmore Pharma, Reg. No. 032206 as me too for the applied formulation. Revised label claim is as under: Each ml contains: Oxfendazole……62.50mg Oxyclozanide……..22.65mg Cobalt Sulphate……1.67mg Sodium Selenite……0.50mg
	Remarks of the Evaluator PEC-XIII	• Current GMP status could not be confirmed.
	Decision M-307: Deferred for updated status of GMP of the firm from QA & LT Division. **Firm reply:** Firm submit copy of GMP certificate dated 14-11-2023, Inspection dated 03-04-2023.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1634.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Clozasol Gold Drench
	Composition	Each 100ml contains: Levamisole (HCl)…… …….3gm Oxyclozanide……..6gm Cobalt Sulphate…….0.334gm Sodium Selenite……..…0.1gm
	Diary No. Date of R & I & fee	Dy.No.438 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	On application, following formulation is applied: Each ml contains: Oxfendazole……..94mg Oxyclozanide…….……34mg Cobalt Sulphate……..…3.82mg Sodium Selenite……0.50mg • Me- too status could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for following reasons: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Different compositions have been applied in different parts of dossier.
	Submission of the firm:	Firm has provided Helmex Gold Drench of M/s Selmore Pharma, Reg. No. 057005 as me too for the applied formulation and further submitted that their correct formulation is as under: Each 100ml contains: Levamisole (HCl)…….3gm Oxyclozanide……..……..6gm

		Cobalt Sulphate…….0.334gm Sodium Selenite……..…0.1gm
	Remarks of the Evaluator PEC-XIII	• Current GMP status could not be confirmed.
	Decision M-307: Deferred for updated status of GMP of the firm from QA & LT Division. **Firm reply:** Firm submit copy of GMP certificate dated 14-11-2023, Inspection dated 03-04-2023.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter**		
1635.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Clozasol Plus Drench
	Composition	Each 100ml contains: Levamisole (HCl)……1.50gm Oxyclozanide……..3gm Cobalt Sulphate……0.167gm Sodium Selenite……...0.05gm
	Diary No. Date of R & I & fee	Dy.No.444 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	• Me- too could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm.
	Submission of the firm:	Firm has provided LEZAN DRENCH of M/s IZFAAR PHARMACEUTICAL, Reg. No. 095637 as me too for the applied formulation.
	Remarks of the Evaluator PEC-XIII	• Current GMP status could not be confirmed.
	Decision M-307: Deferred for updated status of GMP of the firm from QA & LT Division. **Firm reply:** Firm submit copy of GMP certificate dated 14-11-2023, Inspection dated 03-04-2023.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter..**		
1636.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Combimit Drench
	Composition	Each ml contains: Oxyclozanide .....94mg Oxfendazole.....34mg Cobalt sulphate.....3.82mg Sodium selenite.....0.50mg
	Diary No. Date of R & I & fee	Dy.No.443 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled

	Me-too status	Combiox Drench of M/s Selmore Pharma (Pvt.) Ltd Multan Road Lahore 057004.
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	• On Form- 5, Clozasol Gold Drench brand name is applied while fee- challan is of Combimit Drench.
	Decision of 296th meeting of Registration Board:	Deferred for applied composition as on Form- 5, "Clozasol Gold Drench" brand name is applied while fee- challan is of "Combimit Drench".
	Submission of the firm:	Firm has submitted that brand name Clozasol Gold Drench was mentioned by mistake on form-5 and also provided revised form-5. They further provided undertaking that the same fee slip will not be used for any other product.
	Remarks of the Evaluator PEC-XIII	• Current GMP status could not be confirmed.
	Decision M-307: Deferred for updated status of GMP of the firm from QA & LT Division. **Firm reply:** Firm submit copy of GMP certificate dated 14-11-2023, Inspection dated 03-04-2023.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1637.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Doximit- C Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate ….....25,00,000 IU Tylosin as Tartrate …….....100mg Doxycycline as Hyclate ……....100mg Bromhexine as HCl …..... .....…5mg
	Diary No. Date of R & I & fee	Dy.No.439 dated 03-01-2019 Rs.20,000/- 03-01-2019.
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled.
	Me-too status	Could not be confirmed.
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Previous Remarks of the Evaluator PEC-XIII (a)	• Me- too could not be confirmed.
	Decision of 296th meeting of Registration Board:	Deferred for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission of the firm:	Firm has provided Doximac-C water soluble powder, Reg. No. 049530, Prix Pharma as me too for the applied formulation.
	Remarks of the Evaluator PEC-XIII	• Current GMP status could not be confirmed.
	Decision M-307: Deferred for updated status of GMP of the firm from QA & LT Division. **Firm reply:** Firm submit copy of GMP certificate dated 14-11-2023, Inspection dated 03-04-2023.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1638.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Amcocin Injection

	Composition	Each ml Contains: Amoxicillin Trihydrate…100mg Colistin Sulphate…250,000IU
	Diary No. Date of R& I & fee	Dy.No 4585 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "As per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 6269502340. • Provided conversion of Colistin sulphate from IU to kg as mentioned below: Colistin Sulphate 250,000 IU = 13.15mg **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Decision M-323: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. **Firm reply:** Firm submit generic Colimoxin Injection (Reg. 034576)	
Decision: Approved **The firm shall submit fee Rs. 30,000/- for correction in salt form prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1639.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Moxidek Injection
	Composition	Each vial contains: Moxidectin…….1% w/v
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 63 dated 10-09-2013 Rs.20,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cydectin 1% Injectable **50ml** of M/s Rhone Poluene (Pvt) Ltd Lahore (Reg. No. 019034) **could not be confirmed in the applied fill volume**
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	**Veterinary Liquid injection (General) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008 **Shortcomings:**

		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the **same fill volume as applied** alongwith registration number, brand name and name of firm.
	Decision M-323: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the same fill volume as applied alongwith registration number, brand name and name of firm. **Firm reply as under:** Firm requested to issued pack size 50ml as per generic. Firm submitted full fee Rs. 30,000/- slip no. 84013697905 dated Nov 15, 2023. **Decision: Approved**	

1640.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Empoxin 250 Injectable Solution
	Composition	Each gm contains: Oxytetracycline HCl…200mg Neomycin Sulphate…250mg Colistin Sulphate…0.3 MIU
	Diary No. Date of R& I & fee	Dy.No 28427 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml vial; Decontrolled
	Me-too status	
	GMP status	
	Remarks of the Evaluator [x]	**Sterile Liquid Injectable (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020. **Shortcomings:** • **Oxytetracycline HCl…200mg/gm, Neomycin Sulphate…250mg/gm and Colistin Sulphate…0.3 MIU/gm** is mentioned on Form-5 while **Oxytocin 10, 00,000 IU/ 100L** is mentioned in rest of the dossier; clarification is required for which formulation you want to apply this dossier. • Provide conversion of Colistin Sulphate from MIU to milligrams.
	Decision M-324: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months. **Firm reply:** Firm inform that they have apply following composition: Each ml contains: Oxytocin ….10IU and accordingly they attach copy of Form-5 and generic Oxytocin SYN Injection (Reg. 019928) Firm submit panel inspection report showing Dedicated sterile liquid injectable veterinary (Hormones/steroid) dated 19-01-2024.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		

1641.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Bactiplus-C WS Powder
	Composition	Each Kg Contains: Vitamin A...0.8gm Vitamin D3...0.16gm Vitamin E...0.38gm Vitamin B1...1gm Vitamin B2...1.25gm Vitamin B6...4gm Vitamin B12...0.001gm Nicotinamide...6.25gm Sodium Chloride...2.5gm Magnesium Sulphate...25gm Manganese Sulphate...10gm Zinc Sulphate...400mg Copper Sulphate...50mg Cobalt Sulphate...100mg Potassium Iodide...0.5gm Sodium Selenite...0.01gm Di Calcium Phosphate...120gm
	Diary No. Date of R& I & fee	Dy.No 28422 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Vitamin and minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [x]	**Oral Jar Powder Veterinary (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of availability of testing facility required for applied formulation along with drug product analytical procedure.
	Decision M-324: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months. **Firm Reply:** Firm have informed that they apply following composition: Each gm contains: Each gm contains: Oxytetracycline HCl…250mg Neomycin Sulphate…250mg Colistin Sulphate…0.3 MIU Accordingly, firm submit generic Oxycol forte Powder (Reg. 071068)	
Decision: Approved **The firm shall submit full fee Rs. 7500/- for revised formulation prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		

1642.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Trumate Injectable Solution
	Composition	Each ml Contains: Cloprostenol Sodium 263mcg eq. to Cloprostenol …250mcg
	Diary No. Date of R& I & fee	Dy.No 28411 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Prostaglandin F-2-alpha analogue
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	2ml vial; Decontrolled
	Me-too status	Prostenol Injection (2ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 029611)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision M-324: Deferred for submission of evidence of approval of required manufacturing facility from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months. **Firm reply:** **Sterile Liquid Injectable (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020.	
Decision: Approved		
1643.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Glucolac Injection
	Composition	Each ml Contains: Calcium Gluconate…440mg
	Diary No. Date of R& I & fee	Dy.No 28430 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Calcium supplement
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Sterile Liquid Injectable (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision M-324: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months. **Firm Reply:** **Firm submit revised formulation with generic, which is as under:** Each ml Contains:	

	Calcium Gluconate…440mg Boric Acid……60mg Firm submit generic Glucal 44 Injection (Reg. 087820)	
Decision: Approved		
1644.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Em-Calcium Injection
	Composition	Each ml Contains: Calcium Gluconate…208.30mg Magnesium Hypophosphite…53.30mg Calcium D Saccharate…10mg Magnesium Chloride…20mg Boric Acid…43.3mg Dextrose…200mg
	Diary No. Date of R& I & fee	Dy.No 28424 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Calcium and Magnesium Supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	450ml vial; Decontrolled
	Me-too status	Calpho-M Injection (450ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043146)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Veterinary Liquid vials injection (LVP)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision M-324: Deferred for submission of evidence of approval of required manufacturing facility from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months. **Firm reply:** Firm submit panel inspection report showing Sterile liquid veterinary injectable (G) including two separate filling lines for SVP & LVP dated 19-01-2024.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for specification correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter**		
1645.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Bou-Man Solution for Injection
	Composition	Each ml Contains: Buserelin Acetate 0.0042mg Eq. To Buserelin…0.004mg
	Diary No. Date of R& I & fee	Dy.No 28423 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Gonadorelin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml vial; Decontrolled
	Me-too status	Buserovet Injection (5ml) of M/s VETZ Pharmaceuticals (Pvt) Limited, Kotri. (Reg. No. 109961)

	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Veterinary Liquid vials injection (Hormone)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility i.e., Veterinary Liquid vials injection (Hormone) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months. **Firm reply:** Firm submit panel inspection report showing Dedicated sterile liquid injectable veterinary (Hormones/steroid) dated 19-01-2024.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for specification correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1646.	Name and address of manufacturer / Applicant	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isoden Suspension for Injection
	Composition	Each ml Contains: Isoflupredone Acetate…2mg
	Diary No. Date of R& I & fee	Dy.No 28432 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Synthetic corticosteroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml vial; Decontrolled
	Me-too status	Isopred Suspension for Injection (10ml) of M/s Alina Combine Pharmaceutical Karachi. (Reg. No. 063701)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Injectable (Steroid)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision M-324: Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid Injection (Steroid) Veterinary section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months. **Firm reply:** Firm submit panel inspection report showing Dedicated sterile liquid injectable veterinary (Hormones/steroid) dated 19-01-2024.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for specification correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1647.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Me Sel Oral Liquid
	Composition	Each ml contains: Vitamin E (Alpha Tocopherol acetate) …100mg Sodium Selenite…2mg
	Diary No. Date of R& I & fee	Dy.No 9883 dated 30-03-2021 Rs.20,000/- dated 30-03-2021

	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml and 5000ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator X	. **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision M-329: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm along with testing facility. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. **Firm reply:** Firm submit revised formulation along with generic, which is as under: Each 100ml contains: Vitamin E (Alpha Tocopherol acetate) …12gm Sodium Selenite…220mg Generic details: Fizisel Oral Liquid (Reg. 081340)	
Decision: Approved **The firm shall submit fee Rs. 7500/- for specification correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1648.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mectin-V Injection 50ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 4075 dated 04-02-2021 Rs.20,000/- dated 04-02-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ivoron Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No.112248)
	GMP status	
	Remarks of the Evaluator X	**Shortcomings:** Latest GMP inspection report conducted within the period of last three years. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision 329: Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	

	Firm Reply: Firm submitted GMP dated 02-01-2024 showing liquid injectable section.	

Decision: Approved

The firm shall submit fee Rs. 7500/- for specification correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1649.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	N-Tox Powder
	Composition	Each gram contains: Methenamine ……700mg Sodium Citrate ……..…100mg Citric Acid ……100mg Vitamin B1 ……..…8mg Vitamin B6 ……...…9.2mg Vitamin K3 ……..…2mg
	Diary No. Date of R& I & fee	Dy. No 25608 dated 30-09-2020 Rs.20,000/- dated 29-09-2020
	Pharmacological Group	Antibacterial, diuretic, **antifungal**
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • Firm shall submit fee of Rs.7,500/- for correction in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Firm reply:

Decision of M-330	**Firm reply**
Firm shall submit fee of Rs.7,500/- for correction in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Submitted vide slip no. 1708998127 dated Dec 7, 2023.
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	D-TOX Oral powder (Reg. 063806) of M/s Biogen Pharma.

Decision: Approved

1650.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amino-Vita 250ml Injection
	Composition	Each ml contains: L-Carnitine HCl 6.133mg Eq. to L-Carnitine…5mg Thioctic Acid...0.20mg Pyridoxine HCl...0.15mg Cyanocobalamin...0.03mg

		D L-Acetylmethionine...20mg L-Arginine...2.40mg L-Ornithine HCl 1.532mg Eq. to L-Ornithine...1.20mg L-Citrulline...1.20mg L-Lysine HCl 0.625mg Eq. to L-Lysine...0.50mg Glycine...1.50mg Taurine...1.50mg Aspartic Acid...1.50mg Glutamic Acid...1.50mg Fructose...50mg Sorbitol...80mg
	Diary No. Date of R& I & fee	Dy.No 23706 dated 30-08-2021 Rs.30,000/- dated 23-08-2021 (slip No. 12207413635)
	Pharmacological Group	Vitamins & other micronutrients
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	250ml vial; Decontrolled
	Me-too status	Multimino-V Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 058712)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • The firm has submitted list of equipments for confirmation of testing facility. **Shortcomings:** • Confirmation of relevant manufacturing facility i.e. **Liquid injectable LVP (veterinary)**
	Decision M-330: Deferred for confirmation of relevant manufacturing facility. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. **Reply of the Firm:** Firm submit Liquid injectable general section approval along with detail of equipment's.	
Decision: Approved		
1651.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Leva Par 50 Oral Powder
	Composition	Each gram contains: Levamisole HCl…0.5mg
	Diary No. Date of R& I & fee	Dy.No 8054 dated 25-03-2022 Rs.30,000/- dated 18-03-2022 (slip No. 20238516196)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	5gm, 10gm, 50gm, 100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral Powder section (General) Veterinary** confirmed vide letter No. 1-36/2006-Lic (Vol-I) dated 26-09-2019 **Shortcomings:** • Clarification regarding the applied formulation is required since Levamisole HCl…..**500mg/Kg** mentioned in cover

		letter while Levamisole HCl…..**500gram/Kg** is mentioned in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Firm reply:

Decision of M-331	**Firm reply**
Clarification regarding the applied formulation since Levamisole HCl…..500mg/Kg mentioned in cover letter while Levamisole HCl…..500gram/Kg is mentioned in Form-5.	The required formulation is as per form-5 which is Levamisole HCl…..500gram/Kg
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Anthiy Powder (Reg. 044964) of M/s Leads Pharma

Decision: Approved

1652.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Farmox LA Suspension for Injection 250ml
	Composition	Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 9046 dated 08-04-2022 Rs.30,000/- dated 01-04-2022 (slip No. 327880350866)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid Injectable (Penicillin) LVP** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification regarding the applied formulation is required since Amoxicillin Trihydrate Eq. To Amoxicillin Base…**150mg** is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…**200mg** is mentioned in label claim in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Decision of M-331st meeting of RB	**Firm reply**
Latest GMP inspection report conducted within the period of last three years.	Submitted GMP inspection report dated 13-06-2018, 10-10-2018 & 11-12-2018.
Confirmation of relevant manufacturing facility	**Not submitted.**
Clarification regarding the applied formulation since Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin	Firm submit revised form-5 with following composition: Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg

	Base…200mg is mentioned in label claim in Form-5.	With fee Rs. 30,000/- vide slip no. 507213757 dated Jan 15, 2024.
	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Novamox L.A Injection (Reg. # 043135) of M/s Selmore.

Decision: Deferred for Confirmation of relevant manufacturing facility

1653.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Farmox LA Suspension for Injection 50ml
	Composition	Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 9044 dated 08-04-2022 Rs.30,000/- dated 01-04-2022 (6654135137)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid Injectable (Penicillin)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification regarding the applied formulation is required since Amoxicillin Trihydrate Eq. To Amoxicillin Base…**150mg** is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…**200mg** is mentioned in label claim in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Decision of M-331st meeting of RB	**Firm reply**
Latest GMP inspection report conducted within the period of last three years.	Submitted GMP inspection report dated 13-06-2018, 10-10-2018 & 11-12-2018.
Confirmation of relevant manufacturing facility	**Not submitted.**
Clarification regarding the applied formulation since Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg is mentioned in label claim in Form-5.	Firm submit revised form-5 with following composition: Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg With fee Rs. 30,000/- vide slip no. 8408945730 dated Jan 15, 2024.
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Novamox L.A Injection (Reg. # 043135) of M/s Selmore.

Decision: Deferred for Confirmation of relevant manufacturing facility

1654.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.

	Brand Name +Dosage Form + Strength	Eto-Iver 10.2 Injection 10ml
	Composition	Each ml contains: Ivermectin…10.2mg
	Diary No. Date of R& I & fee	Dy.No 18194 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 0301008528)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid Injectable (General)Veterinary section** from CLB. • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Firm reply:

Decision of M-331	**Firm reply**
Approval of Liquid Injectable (General)Veterinary section from CLB.	Submitted Approval of Liquid Injectable (General)Veterinary section from CLB.
Latest GMP inspection report conducted within the period of last three years.	GMP certificate inspection dated 14-10-2021.
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	ETO-Iver-10.2 Injection (Reg.109831) 50ml

Decision: Approved

1655.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto-Iver 10.2 Injection 100ml
	Composition	Each ml contains: Ivermectin…10.2mg
	Diary No. Date of R& I & fee	Dy.No 18195 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 42297587)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid Injectable (General)Veterinary section** from CLB. • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **in the applied pack size** alongwith registration number, brand name and name of firm.

	Decision of M-331	**Firm reply**
	Approval of Liquid Injectable (General)Veterinary section from CLB.	Submitted Approval of Liquid Injectable (General)Veterinary section from CLB.
	Latest GMP inspection report conducted within the period of last three years.	GMP certificate inspection dated 14-10-2021.
	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	ETO-Iver-10.2 Injection (Reg.109831) 50ml
	Decision: Approved	
1656.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter-Bupra Injection 20ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 18190 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 0874243473)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	20ml,: Decontrolled
	Me-too status	Empilex Injection (20ml) of M/s Manhattan Pharma, Karachi. (Reg. No. 109090)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision of M-331	**Firm reply**
	Approval of **relevant manufacturing facility**	Submitted Approval of Liquid Injectable (General)Veterinary section from CLB.
	Latest GMP inspection report conducted within the period of last three years.	GMP certificate inspection dated 14-10-2021.
	Decision: Approved	
1657.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ticid Injection 100ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 18189 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 3366495948)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Gtrise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112180)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** • Latest GMP inspection report conducted within the period of last three years.

		• Firm shall submit fee of Rs.30000/- for correction in formulation (salt form) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Decision of M-331	**Firm reply**
Approval of relevant manufacturing facility	Submitted Approval of Liquid Injectable (General)Veterinary section from CLB.
Latest GMP inspection report conducted within the period of last three years.	GMP certificate inspection dated 14-10-2021.
The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	Challan No. 27891580044 submission dated Dec 7, 2023

Decision: Approved subject to full fee submission as per SRO for salt form correction.

1658.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ivozon 10.5% Injection 100ml
	Composition	Each ml contains: Ivermectin ……..105mg
	Diary No. Date of R& I & fee	Dy. No. 23361 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 2834323716)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP (Vet.) Specification
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Mac Rold 10.5% Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 106817)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision 331: Deferred for clarification of the applied strength Firm reply: This is for marketing purpose as different clients demands different strengths.	
Decision: Approved		
1659.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ivozon 10.5% Injection 10ml
	Composition	Each ml contains: Ivermectin ……..105mg
	Diary No. Date of R& I & fee	Dy. No. 23359 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 3070188840)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP (Vet.) Specification
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Mac Rold 10.5% Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 106815)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for clarification of the applied strength Firm reply:	

	This is for marketing purpose as different clients demands different strengths.	
Decision: Approved		
1660.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ivozon 10.5% Injection 50ml
	Composition	Each ml contains: Ivermectin ……..105mg
	Diary No. Date of R& I & fee	Dy. No. 23360 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 9749633264)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP (Vet.) Specification
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Mac Rold 10.5% Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 106816)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for clarification of the applied strength Firm reply: This is for marketing purpose as different clients demands different strengths.	
Decision: Approved		
1661.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Floxon Extra Injection 10ml
	Composition	Each ml contains: Flunixin as Meglumin … 83mg
	Diary No. Date of R& I & fee	Dy. No. 23392 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 8711702616)
	Pharmacological Group	Analgesic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply:** Firm submitted generic Nixsym Injection of M/s Symans (Reg.#063852)	
Decision: Approved		
1662.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Floxon Extra Injection 50ml
	Composition	Each ml contains: Flunixin as Meglumin … 83mg

	Diary No. Date of R& I & fee	Dy. No. 23393 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 668454922966)
	Pharmacological Group	Analgesic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply:** Firm submitted generic Nixsym Injection of M/s Symans (Reg.#063852)	
Decision: Approved		
1663.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Metazon Injection 100ml
	Composition	Each 100ml contains: L-Carnitine …….. 500mg Thioctic Acid …….. 20mg Pyridoxine Hydrochloride ……. 15mg Cyanocobalamine …… 3mg DL-Acetyl methionine …….. 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …….. 50mg Glycine …… 150mg Taurine …….. 150mg Aspartic Acid ……..… 150mg Glutamic Acid ……. 150mg Fructose ……. 5000mg Sorbitol …….. 8000mg
	Diary No. Date of R& I & fee	Dy. No. 23396 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 3628565723)
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) **Could not be confirmed in the applied combination**
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm has submitted evidence of testing facility **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply as under:** As per decision of the Board firm submit Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) as generic.	

Decision: Approved		
1664.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Metazon Injection 250ml
	Composition	Each 100ml contains: L-Carnitine …….. 500mg Thioctic Acid …….. 20mg Pyridoxine Hydrochloride ……. 15mg Cyanocobalamine …… 3mg DL-Acetyl methionine …….. 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …….. 50mg Glycine …… 150mg Taurine …….. 150mg Aspartic Acid ……...… 150mg Glutamic Acid ……. 150mg Fructose ……. 5000mg Sorbitol …….. 8000mg
	Diary No. Date of R& I & fee	Dy. No. 23397 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 385227717973)
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	250ml, Decontrolled
	Me-too status	Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) **Could not be confirmed in the applied combination**
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm has submitted evidence of relevant testing and manufacturing facility **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply as under:** As per decision of the Board firm submit Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) as generic.	
Decision: Approved		
1665.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Metazon Injection 500ml
	Composition	Each 100ml contains: L-Carnitine …….. 500mg Thioctic Acid …….. 20mg Pyridoxine Hydrochloride ……. 15mg Cyanocobalamine …… 3mg DL-Acetyl methionine …….. 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …….. 50mg

		Glycine …… 150mg Taurine …….. 150mg Aspartic Acid ……...… 150mg Glutamic Acid ……. 150mg Fructose ……. 5000mg Sorbitol …….. 8000mg
	Diary No. Date of R& I & fee	Dy. No. 23398 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 3466697778)
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	500ml, Decontrolled
	Me-too status	Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) **Could not be confirmed in the applied combination**
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm has submitted evidence of relevant testing and manufacturing facility **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 331: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Firm reply as under:** As per decision of the Board firm submit Multimino-V Injection of M/s. Selmore Pharma (Reg. No. 058712) as generic.	
Decision: Approved		
1666.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Pentavetz Injection 50ml
	Composition	Each ml contains: Cyanocobalamine…0.5mg Sodium Selenite…1mg Adenosine Triphosphate Tetrasodium Dihydrate Salt…1mg Potassium Aspartate…10mg Magnesium Aspartate…15mg
	Diary No. Date of R& I & fee	Dy.No 861 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-stress
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Biosal Injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision of 329th meeting: Deferred for confirmation of relevant testing facility.	
	Updated status: The firm has submitted that all minerals in the applied product shall be tested through titration method and there is no need of Atomic Absorption Spectrophotometer. Analytical methods are also submitted.	

	Decision M-333: Deferred for submission of analytical method validation studies for the proposed drug product test method. **Firm reply:** Firm submitted protocol for analytical method validation studies. .	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter**		
1667.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Lactomin Gold granules
	Composition	Each gram contains: Vitamin A……0.8mg Vitamin D3……..0.16mg Vitamin E…….0.38mg Vitamin B1…….1mg Vitamin B2…….1.25mg Vitamin B12…….0.001mg Vitamin B3…….6.25mg Copper sulphate…….0.25mg Magnesium sulphate…….25mg Calcium Chloride…….0.023mg Zinc sulphate…….2.17mg Manganese sulphate……10mg Potassium iodide…….0.5mg Sodium selenite…….0.01mg DCP (Phosphorus)…….150mg Sodium chloride…….120mg Vitamin B6…….4mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 36 dated 10-07-2009 Rs.8,000/- dated 10-07-2009; Rs.12,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Multivitamins and minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No.058842)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder (General) section** granted vide letter No. F. 1-30/2001-Lic dated 27-03-2007 • **Target species:** Cattle, horse, calves, foal, sheep, goat
	Decision M-333: Deferred for confirmation of relevant testing facility required for applied formulation. **Firm reply:** Firm inform that they tested all minerals through titration method and vitamins through HPLC method.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		

1668.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lechlor Spray
	Composition	Each ml contains: Chlortetracycline HCl…15.2mg
	Diary No. Date of R& I & fee	Dy.No 26523 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 922799682324)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	150ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Domestic animals **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision 334: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee. **Firm reply:** Firm submitted generic Biochlor Aerosol spray (Reg. 088094) of M/s Selmore.	
Decision: Approved **The firm shall submit fee Rs. 7500/- for correction in specification prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**		
1669.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-25 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…0.25mg
	Diary No. Date of R& I & fee	Dy.No 6889 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 327: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: **Firm has submitted full fee dated Dec 22, 2023 11:02 AM (Receipt # 4102403443) along with revised composition as per generic Enrotin 25% oral solution, as per following details:** Each ml Contains: Enrofloxacin…250mg	
Decision: Approved		

1670.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fexazol Plus Oral Drench
	Composition	Each ml contains: Oxfendazole…25mg Cobalt Sulphate…2mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 6849 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 327: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Firm has submitted reply dated Dec 22, 2023 11:03 AM with full fee Rs. 30,000/- (Challan# 06190227154) along with revised composition as per generic Jfxantox-Plus Drench(Reg.#039989), details as under: Each ml contains: Oxfendazole…25mg Cobalt Sulphate…2mg Sodium Selenite…0.05mg	
Decision: Approved		
1671.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 10/50 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…5,00,00 IU
	Diary No. Date of R& I & fee	Dy.No 6892 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 327: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply:	

	Firm has submitted reply dated Dec 22, 2023 11:04 AM with full fee Rs. 30,000/- (Challan# 2323444657) along with revised composition as per generic EnroSheph-C Oral Solution(Reg.#079143), details as under: Each 100ml contains: Enrofloxacin…10g Colistin Sulphate…50 MIU	
Decision: Approved		
1672.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Oral Liquid
	Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate) …5mg Vitamin A (retinol oily form) …0.03 MIU Vitamin K3 (Menadione) …0.600mg Vitamin D3 (calcifediol) …0.001 MIU
	Diary No. Date of R& I & fee	Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding applied strength since Vitamin E.....5000mg/1000ml is mentioned on cover letter while Vitamin E.....600mg/1000ml is mentioned in label claim on Form-5. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision 327: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Firm has submitted reply dated Dec 22, 2023 11:04 AM with full fee Rs. 30,000/- (Challan# 32322227) along with revised composition as per generic Adekbar Oral Liquid (Reg.#073950), details as under: Each 1000ml contains: Vitamin A …30MIU Vitamin D3 …1MIU Vitamin E …5000mg Vitamin K …..6000mg	
Decision: Approved		
1673.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Gold Oral Liquid
	Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate) …15mg Vitamin A (retinol oily form) …2,500 IU Vitamin K3 (Menadione) …2.5mg Vitamin D3 (calcifediol) …250 MIU
	Diary No. Date of R& I & fee	Dy.No 6882 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X] **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision 327: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Firm has submitted reply dated Dec 22, 2023 11:05 AM with full fee Rs. 30,000/- (Challan# 1084116169) along with revised composition as per generic Adek GOLD Oral Solution (Reg.#063813), details as under: Each Liter Contains:- Vitamin A……25MIU. Vitamin D3…..250000IU Vitamin E…….15000mg Vitamin K3……2500mg	
Decision: Approved		

Case no. 05 Routine Registration applications

i. Human

1674.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Capsule (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 34820 dated 01-12-2022
	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 10293836409
	The proposed proprietary name / brand name	**LIGAB CAPSULES 75mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ….75mg
	Pharmacotherapeutic Group of (API)	Pregabalin is antiepileptic drug and an analogue of the neurotransmitter gamma-aminobutyric acid (GABA)

	Pharmaceutical form of applied drug	White cap and white body EHGC shell size "3" filled with white color powder.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica Capsules (Approved by USFDA)
	For generic drugs (me-too status)	Gabica 75mg Capsules of M/s Getz Pharma (Pvt) Limited, Karachi.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Address: Block No. 251-252 Sachin- Magdalla Road GIDC-Sachin, Dist: Surat (Gujarat), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Pregabalin is B.P. grade, the firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Pregabalin at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (PG163006, PG163007, PG163008)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the Innovator product Lyrica 75mg Capsules (Batch No. EP0926) manufactured by M/s Pfizer Germany. Firm has submitted Comparative Dissolution Profile of their product against the Innovator product Lyrica 75mg Capsules (Batch No. EP0926) manufactured by M/s Pfizer Germany.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug substance as well as analytical method validation study report for drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Pregabalin**: M/s CTX Lifesciences Pvt. Ltd, Address: Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Dist: Surat (Gujarat), INDIA.		
API Lot No.	20PG00072		
Description of Pack (Container closure system)	02 alu-alu blister of 7 capsules, packed in cardboard box (Box of 14 capsules)		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGCap-001	PGCap-002	PGCap-003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	07-05-2021	07-05-2021	07-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP issued dated 30-05-2022 valid up to 29-05-2025 issued by Food & Drugs Control Administration, Block No. 8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 00833/2020-DRAP(P)/3568 for 2.000 Kg Pregabalin cleared on 23-09-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator: monograph is available in BP Submitted for consideration of the Board		
Decision: Approved		

1675.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Capsule (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 34821 dated 01-12-2022
	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 408868180
	The proposed proprietary name / brand name	**LIGAB CAPSULES 150mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ….150mg
	Pharmacotherapeutic Group of (API)	Pregabalin is antiepileptic drug and an analogue of the neurotransmitter gamma-aminobutyric acid (GABA)
	Pharmaceutical form of applied drug	White cap and white body EHGC shell size “2” filled with white color powder.
	Reference to Finished product specifications	Innovator’s specifications
	Proposed Pack size	7’s, 10’s, 14’s, 20’s, 28’s and 30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica Capsules (Approved by USFDA)
	For generic drugs (me-too status)	Gabica 150mg Capsules of M/s Getz Pharma (Pvt) Limited, Karachi.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Address: Block No. 251-252 Sachin- Magdalla Road GIDC-Sachin, Dist: Surat (Gujarat), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Pregabalin is B.P. grade, the firm submitted detail of

		nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Pregabalin at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (PG163006, PG163007, PG163008)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the Innovator product Lyrica 150mg Capsules (Batch No. FF1126) manufactured by M/s Pfizer Germany. Firm has submitted Comparative Dissolution Profile of their product against the Innovator product Lyrica 150mg Capsules (Batch No. FF1126) manufactured by M/s Pfizer Germany.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug substance as well as analytical method validation study report for drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Pregabalin**: M/s CTX Lifesciences Pvt. Ltd, Address: Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Dist: Surat (Gujarat), INDIA.		
	20PG00072		
Description of Pack (Container closure system)	02 alu-alu blister of 7 capsules, packed in cardboard box (Box of 14 capsules)		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGCap-004	PGCap-005	PGCap-006
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	07-05-2021	07-05-2021	07-05-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP issued dated 30-05-2022 valid up to 29-05-2025 issued by Food & Drugs Control Administration, Block No. 8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 00833/2020-DRAP(P)/3568 for 2.000 Kg Pregabalin cleared on 23-09-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator: monograph is available in BP Submitted for consideration of the Board		
Decision: Approved		
1676.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Capsule (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 34822 dated 01-12-2022

	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 41248778
	The proposed proprietary name / brand name	**LIGAB CAPSULES 300mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ….300mg
	Pharmacotherapeutic Group of (API)	Pregabalin is antiepileptic drug and an analogue of the neurotransmitter gamma-aminobutyric acid (GABA)
	Pharmaceutical form of applied drug	Orange cap and white body EHGC shell size "0" filled with white color powder.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica Capsules (Approved by USFDA)
	For generic drugs (me-too status)	Gabica 300mg Capsules of M/s Getz Pharma (Pvt) Limited, Karachi.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Address: Block No. 251-252 Sachin- Magdalla Road GIDC-Sachin, Dist: Surat (Gujarat), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Pregabalin is B.P. grade, the firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Pregabalin at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (PG163006, PG163007, PG163008)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the product Gabica 300mg Capsules

		(Batch No. 239C27) manufactured by M/s Getz Pharma Karachi. Firm has submitted Comparative Dissolution Profile of their product against the product Gabica 300mg Capsules (Batch No. 239C27) manufactured by M/s Getz Pharma Karachi.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug substance as well as analytical method validation study report for drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Pregabalin**: M/s CTX Lifesciences Pvt. Ltd, Address: Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Dist: Surat (Gujarat), INDIA.		
	20PG00072		
Description of Pack (Container closure system)	02 alu-alu blister of 7 capsules, packed in cardboard box (Box of 14 capsules)		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGCap-007	PGCap-008	PGCap-009
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	07-05-2021	07-05-2021	07-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP issued dated 30-05-2022 valid up to 29-05-2025 issued by Food & Drugs Control Administration, Block No. 8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 00833/2020-DRAP(P)/3568 for 2.000 Kg Pregabalin cleared on 23-09-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator: monograph is available in BP Submitted for consideration of the Board		
Decision: Approved		
1677.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33131 dated 18-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 615590109339
	The proposed proprietary name / brand name	**XARIA TABLETS 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rivaroxaban….20mg
	Pharmacotherapeutic Group of (API)	Antithrombotic (Direct factor Xa inhibitors)
	Pharmaceutical form of applied drug	Pink color, round biconvex film coated tablet plain on both sides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarelto Tablets (Approved by USFDA)
	For generic drugs (me-too status)	Xcept Tablets of M/s PharmaEvo
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Rivaroxaban at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (20160701S, 20160702S, 20160703S)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical equivalence and Comparative Dissolution Profile of their product against the Innovator product Xarelto Tablets 20mg (Batch No. BXJ6901) manufactured by M/s Bayer AG, Germany.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China		
API Lot No.	09-20200303S		
Description of Pack (Container closure system)	01 Alu-PVC blister of 20 tablets, packed in cardboard box (Box of 20 tablets)		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RVTab-007	RVTab-008	RVTab-009
Batch Size	750 Tablets	750 Tablets	750 Tablets
Manufacturing Date	05-2021	05-2021	05-2021

Date of Initiation	18-06-2021	18-06-2021	18-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued dated 27-11-2020 valid up to 26-11-2025 issued by Jiangxi Provincial Medical Products Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 001054/2020-DRAP(P)/4433 for 0.25 Kg Rivaroxaban cleared on 16-11-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 75% in 20 minutes, justify.	It is to inform you that while assigning limits for dissolution we consult USFDA dissolution database instead of US FDA review document of innovator's product. As per USFDA dissolution data base recommended time points for drug release are 10min, 15min, 20min, 30min and 45min whereas more than 85% release was also observed at 15min and more than 90% release was observed at 20 minutes that's why as per our practice we declare the dissolution limits as NLT 75% in 20 minutes. Furthermore, now drug product covered in B.P. and as per B.P. monograph dissolution limit is NLT 80 (Q) after 30 minutes which is more broader than our assigned limit .

Decision: Approved

1678.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33129 dated 18-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 501120095610
	The proposed proprietary name / brand name	**XARIA TABLETS 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rivaroxaban….10mg
	Pharmacotherapeutic Group of (API)	Antithrombotic (Direct factor Xa inhibitors)
	Pharmaceutical form of applied drug	Light pink color, round biconvex film coated tablet plain on both sides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarelto Tablets (Approved by USFDA)
	For generic drugs (me-too status)	Xcept Tablets of M/s PharmaEvo
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Rivaroxaban at both accelerated as well as

		real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (20160701S, 20160702S, 20160703S)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical equivalence and Comparative Dissolution Profile of their product against the Innovator product Xarelto Tablets 10mg (Batch No. BXJ8KK1) manufactured by M/s Bayer AG, Germany.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China		
API Lot No.	09-20200303S		
Description of Pack (Container closure system)	01 Alu-PVC blister of 20 tablets, packed in cardboard box (Box of 20 tablets)		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RVTab-001	RVTab-002	RVTab-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	06-07-2021	06-07-2021	06-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued dated 27-11-2020 valid up to 26-11-2025 issued by Jiangxi Provincial Medical Products Administration.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 001054/2020-DRAP(P)/4433 for 0.25 Kg Rivaroxaban cleared on 16-11-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 75% in 20 minutes, justify.	It is to inform you that while assigning limits for dissolution we consult USFDA dissolution database instead of US FDA review document of innovator's product. As per USFDA dissolution data base recommended time points for drug release are 10min, 15min, 20min, 30min and 45min whereas more than 85% release was also observed at 15min and more than 90% release was observed at 20 minutes that's why as per our practice we declare the dissolution limits as NLT 75% in 20 minutes. Furthermore, now drug product covered in B.P. and as per B.P. monograph dissolution limit is NLT 80 (Q) after 30 minutes which is more broader than our assigned limit .

Decision: Approved

1679.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan
	Name, address of Manufacturing site.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet (General) section confirmed vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33130 dated 18-11-2022

	Details of fee submitted	PKR 30,000/- Dated 31-10-2022 Slip No. 0794834509
	The proposed proprietary name / brand name	**XARIA TABLETS 15mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rivaroxaban….15mg
	Pharmacotherapeutic Group of (API)	Antithrombotic (Direct factor Xa inhibitors)
	Pharmaceutical form of applied drug	Brown color, round biconvex film coated tablet plain on both sides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarelto Tablets (Approved by USFDA)
	For generic drugs (me-too status)	Xcept Tablets of M/s PharmaEvo
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Rivaroxaban at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months. Batches: (20160701S, 20160702S, 20160703S)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical equivalence and Comparative Dissolution Profile of their product against the Innovator product Xarelto Tablets 15mg (Batch No. BXJ94D1) manufactured by M/s Bayer AG, Germany.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China		
API Lot No.	09-20200303S		
Description of Pack (Container closure system)	01 Alu-PVC blister of 20 tablets, packed in cardboard box (Box of 20 tablets)		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RVTab-004	RVTab-005	RVTab-006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	28-06-2021	28-06-2021	28-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagen Tablets 10mg & Empagen Tablets 25mg, for which the inspection was conducted on 25-10-2019 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued dated 27-11-2020 valid up to 26-11-2025 issued by Jiangxi Provincial Medical Products Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 001054/2020-DRAP(P)/4433 for 0.25 Kg Rivaroxaban cleared on 16-11-2020 by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sections	**Observations/Deficiencies/ Short-comings**	**Response of the Firm**

3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 75% in 20 minutes, justify.	It is to inform you that while assigning limits for dissolution we consult USFDA dissolution database instead of US FDA review document of innovator's product. As per USFDA dissolution data base recommended time points for drug release are 10min, 15min, 20min, 30min and 45min whereas more than 85% release was also observed at 15min and more than 90% release was observed at 20 minutes that's why as per our practice we declare the dissolution limits as NLT 75% in 20 minutes. Furthermore, now drug product covered in B.P. and as per B.P. monograph dissolution limit is NLT 80 (Q) after 30 minutes which is more broader than our assigned limit .
Decision: Approved		

ii. Veterinary

1680.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amino-Vita Injection 500ml
	Composition	Each ml contains: L-Carnitine HCl 6.133mg Eq. to L-Carnitine…5mg Thioctic Acid...0.20mg Pyridoxine HCl...0.15mg Cyanocobalamin...0.03mg D L-Acetylmethionine...20mg L-Arginine...2.40mg L-Ornithine HCl 1.532mg Eq. to L-Ornithine...1.20mg L-Citrulline...1.20mg L-Lysine HCl 0.625mg Eq. to L-Lysine...0.50mg Glycine...1.50mg Taurine...1.50mg Aspartic Acid...1.50mg Glutamic Acid...1.50mg Fructose...50mg Sorbitol...0.05mg
	Diary No. Date of R& I & fee	Dy.No 33417 dated 21-11-2022 Rs.30,000/- dated 23-08-2021 (slip No. 71479394393)
	Pharmacological Group	Vitamins & other micronutrients
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500ml vial; Decontrolled
	Me-too status	Not submitted
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020. Showing **Liquid injectable (veterinary)**
	Remarks of the Evaluator [X]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied pack size alongwith registration number, brand name and name of firm.	
1681.	Name and address of manufacturer / Applicant	M/s Bio-Labs Pvt. Ltd, plot No. 145 Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Bio-Oxyne 30% Injection
	Composition	Each ml contains: Oxytetracycline HCl eq. to Oxytetracycline…300mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 26853 dated 22-09-2022 Rs.30,000/- dated 22-09-2022, slip no. 14428189553
	Pharmacological Group	Antibiotic tetracycline's , WHO ATC Code. D06AA03
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	100ml glass vial, Decontrolled
	Me-too status	Not submitted
	GMP status	DML renewal report showing Liquid injection general veterinary, date of inspection 08-07-2021, 15-07-2021, 30-07-2021, 03-08-2021.
	Remarks of the Evaluator [X]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied pack size alongwith registration number, brand name and name of firm.	

Case no. 06 Registration applications of import cases

c. Deferred cases

i. Veterinary

1682.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	Name: M/s QAS International Address: Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala Validity: **22-09-2019.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1623 Dated 12-01-2021
	Fee including differential fee	Rs : 100,000 Dated 12-01-2021
	Brand Name +Dosage Form + Strength	Qaslink 4.4% Oral Powder
	Composition	Each gm contains: Lincomycin HCl…44mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	**CIMAvet, Spain approved**

	Me-too status	Colink Powder of M/s Mili Vet Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 112200)
	Detail of certificates attached	1.Original legalized COPP dated 29-01-2019 issued by Spanish agency of Medicines and sanitary products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer. 1. Copy of legalized sole distributor agreement dated 28-02-2019 between applicant and MAH.
	Remarks of the Evaluator X	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** 1.Provide **copy of valid DSL** 2.Provide original legalized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. 3.In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. 4.Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since ***42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala*** is written on form-5A while on copy of DSL ***Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala*** is mentioned
	Decision M-329: Deferred for following: 1.Copy of valid DSL 2.Original legalized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. 3.Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. 4.Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since *42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala* is written on form-5A while on copy of DSL *Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala* is mentioned The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. **Firm Submitted following Reply:** i. Copy of valid DSL No. 09-341-0134-103105D valid upto 13-03-2028. ii. Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. iii. Firm submit justification that *42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala* is their head office while their ware house address changes from *Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala* to Plot no. 153/155 Mustafa abad tehsil kamoke Gujranwala Pakistan Gowown: Opposite Grace Marquee Near Subhan ceramics Main G.T Road Gujranwala as per valid DSL. iv. Firm inform that original legalized valid Power of attorney/sole distributor agreement is already submitted and copy is attached.	
Decision: Approved		
1683.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	**Legible copy not provided**
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain

	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11656 Dated 21-04-2021
	Fee including differential fee	Rs : 100,000 Dated 06-04-2021
	Brand Name +Dosage Form + Strength	Amoxiqas Oral Powder for Use in Drinking Water
	Composition	Each gram contains: Amoxicillin Trihydrate 700mg Eq. to Amoxicillin…610mg
	Finished Product Specification	Ph Eur specifications
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	**CIMAvet, Spain approved** with brand name AMOXIDIAN
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original legalized COPP dated 31-01-2019 issued by Spanish agency of Medicines and Health products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of legalized sole distributor agreement dated 28-02-2019 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Impurity E rises at 3rd and 6th month time point in accelerated stability study.** **Shortcomings:** • Provide legible **copy of valid DSL** • Provide original notarized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Confirmation of **dedicated penicillin manufacturing facility.**
	Decision M-330: Deferred for following: i. legible copy of valid DSL ii. original notarized valid Power of attorney/sole distributor agreement iii. label in accordance with The Drugs (Labeling and Packing) Rules, 1986. iv. confirmation of dedicated penicillin manufacturing facility. v. accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. **Firm Submitted following Reply:** i. Copy of valid DSL No. 09-341-0134-103105D valid upto 13-03-2028. ii. Firm inform that original legalized valid Power of attorney/sole distributor agreement is already submitted and copy is attached. iii. Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. iv. confirmation of dedicated penicillin manufacturing facility v. accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life 24 Months	

Decision: Approved		
1684.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	**Legible copy not provided**
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11657 Dated 21-04-2021
	Fee including differential fee	Rs : 100,000 Dated 06-04-2021
	Brand Name +Dosage Form + Strength	Megluvet Solution for Injection
	Composition	Each ml Contains: Flunixin (Meglumine)…50mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Anti-inflammatory non-steroidal
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Floonix Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112255)
	Detail of certificates attached	➢ Original legalized COPP dated 16-02-2021 issued by Spanish agency of Medicines and Health products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of sole distributor agreement dated 21-01-2021 between applicant and MAH for the applied product.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide legible **copy of valid DSL** • Provide original notarized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision 330: **Deferred for following:** • **legible copy of valid DSL** • **original notarized valid Power of attorney/sole distributor agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.** **Firm Submitted following Reply:** i. Copy of valid DSL No. 09-341-0134-103105D valid upto 13-03-2028. ii. Firm inform that original legalized valid Power of attorney/sole distributor agreement is already submitted and copy is attached. iii. Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. iv. confirmation of dedicated penicillin manufacturing facility	

Decision: Approved subject to fee Rs. 7500/- as per SRO for specification correction		
1685.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1949 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	OTC 20% LA Solution for Injection
	Composition	Each ml Contains: Oxytetracycline as Oxytetracycline Dihydrate…200mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml and 100ml as per FSC
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied pack size**
	Detail of certificates attached	i. Original legalized FSC Ref. No. 609/2020/QLT-CFS dated **30-06-2020** issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: **2years** ii. Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam iii. Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.

	Remarks of the Evaluator X	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** i. Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. **ii.** Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** iii. Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm. iv. Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.

Decision of 329th meeting of RB	**Firm reply**
Original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.	Submitted
Original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.	Submitted
Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.	Zoloxy Injection (Reg. 109924) 50ml
Choice of only one pack size	100ml

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1686.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1948 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Amoxi 500 WSP for Oral Solution
	Composition	Each gram Contains: Amoxicillin Trihydrate 500mg eq to Amoxicillin. ...436mg
	Finished Product Specification	Inhouse specifications

	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	Approved in Spanish Agency for Medicines and Health Products
	Me-too status	Espemox 500mg/G Powder of M/s Poul Med Enterprises, Karachi. (Reg. No. 101523)
	Detail of certificates attached	**i.** Original legalized FSC Ref. No. 605/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years **ii.** Scanned copy of GMP certificate No. 05/19/GCN-GMP dated 16-08-2019 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **iii.** Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator X	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** i. Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. ii. Provide original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission. ii. Confirmation of manufacturing facility.

Decision of 329th meeting of RB	**Firm reply**
Original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.	Submitted
Original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.	Submitted
Confirmation of dedicated manufacturing facility.	Submitted

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1687.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam

	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11784 Dated 20-04-2021
	Fee including differential fee	Rs : 100,000 Dated 20-04-2021
	Brand Name +Dosage Form + Strength	Tylofos Powder for Oral Solution
	Composition	Each gm contains: Fosfomycin Sodium…200mg Tylosin Tartrate…50mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 607/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years ➢ Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Decision of 330th meeting of RB	**Firm reply**
valid legalized original GMP certificate	Submitted
valid legalized original FSC	Submitted
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Submitted

Decision: Approved. The firm shall submit fee Rs. 300,000/- for change in finished product specifications/salt form correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1688.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).

Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
Name of exporting country	China
Type of Form	Form-5A
Diary No. & Date of R& I	Dy. No 25220 Dated 10-09-2021
Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.5456745503)
Brand Name +Dosage Form + Strength	Flumine Plus 8% Injection 100ml
Composition	Each ml contains: Flunixin Meglumine…80mg
Finished Product Specification	USP specifications
Pharmacological Group	NSAID
Shelf life	36 months
Demanded Price	Decontrolled
Pack size	100ml
International availability	N/A
Me-too status	**Could not be confirmed in the applied strength**
Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042901 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply:

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
evidence of applied formulation/drug already approved by DRAP (generic / me-too status)	Not-Submitted.

	along with registration number, brand name and name of firm	
	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.
	Decision: Approved. The firm shall submit fee Rs. 300,000/- for change in finished product specifications/salt form correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1689.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25222 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.047892117)
	Brand Name +Dosage Form + Strength	Neogent 10% Injection
	Composition	Each ml contains: Gentamycin Sulphate…100mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Genster 10 Injection (100ml) of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 111395)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042908 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Firm reply:	
	Decision of M-330	**Firm reply**
	Copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd

		Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
	Notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
	Decision: Approved.	
1690.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25228 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.040060899785)
	Brand Name +Dosage Form + Strength	N-Flor 30 Injection 50ml
	Composition	Each ml contains: Florfenicol…300mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	G-Flor 30% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No.111548)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042913 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

	Decision of M-330	**Firm reply**
	copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
	notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1691.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25226 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.98635031)
	Brand Name +Dosage Form + Strength	Trizole 100ml Injection
	Composition	Each ml contains: Sulfadiazine…200mg Trimethoprim…40mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Kerry T.S Injection (100ml) of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 088829)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042902 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1692.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25219 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.7002853833)
	Brand Name +Dosage Form + Strength	Neomec Super 100ml Injection
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antiparasitic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A

	Me-too status	Iver-Soun Injection (100ml) of M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 109793)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042907 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.

Decision: Approved.

1693.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25221 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.82541926272)
	Brand Name +Dosage Form + Strength	Neomec-DS 100ml Injection
	Composition	Each ml contains: Ivermectin…40mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antiparasitic

	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042905 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	Not-Submitted.
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm

1694.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035

	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25218 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.19448977213)
	Brand Name +Dosage Form + Strength	Neoflox-20 50ml Injection
	Composition	Each ml contains: Enrofloxacin…200mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Bacteriostatic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Enflox-20% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112216)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042906 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1695.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd

		Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25217 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.114907453336)
	Brand Name +Dosage Form + Strength	Tonophos-B 100ml Injection
	Composition	Each ml contains: Tonophosphan…124.4mg Vitamin B12…0.05mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Nutritional supplements
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	New Dechaphosphan Injection (100ml) of M/s Atzan Pharmaceuticals, Sargodha. (Reg. No. 039972)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042903 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Decision of M-330	**Firm reply**
copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy

	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1696.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25223 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.2331535224)
	Brand Name +Dosage Form + Strength	Neo AD3E 100ml Injection
	Composition	Each ml contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Nutrients
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Trivetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079285)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042909 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of M-330	**Firm reply**
	copy of valid DSL	DSL No. 110/2023 Name: M/s Neovet Pharma Pvt Ltd

		Address: Plot No. A 12/37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi, Karachi Godown: House No. A-77, Road No. 07 Cattle colony Karachi Validity: **12-07-2028.** Status: Drug License by way of Wholesale (Form No.7-A).
	notarized original valid Letter of Authorization/ Sole agency certificate	Notarized Letter of Authorization/ Sole agency certificate is copy
	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1697.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24711 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 86671310068)
	Brand Name +Dosage Form + Strength	Actionis Suspension for Injection
	Composition	Each ml Contains: Ceftiofur as Ceftiofur HCl…50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	Calicef 50mg Suspension for Injection **(100ml)** of M/s Orient Animal Health (Pvt) Ltd., Karachi. (Reg. No. 108996)
	Detail of certificates attached	➢ Scanned copy of CoPP dated 17-12-2020 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution valid for 5 years

	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 250ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-330: Deferred for following: • copy of valid DSL • Notarized original valid Letter of Authorization/ Sole agency certificate. • legalized original valid CoPP • confirmation of dedicated manufacturing facility • choice of only one pack size • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm submit following documents:' • copy of DSL valid unto 14-10-2024 • notarized original valid Letter of Authorization/ Sole agency certificate. • Original legalized valid CoPP • confirmation of dedicated manufacturing facility • pack size 100ml • Generic Ceptifi Injection (Reg.#094479)	
Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.		
1698.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24714 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 3126078138)

	Brand Name +Dosage Form + Strength	Amoxoil Retard Suspension for Injection
	Composition	Each ml contains: Amoxicillin (Trihydrate) …150mg
	Finished Product Specification	In house
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	Amocillin 15% Injection **(100ml)** of M/s Eterna Pharma (Pvt) Ltd.,Mirpur, AJK (Reg. No. 113596)
	Detail of certificates attached	➢ Scanned copy of CoPP dated 22-01-2021 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution in **Actionis Suspension for Injection dossier**; valid for 5 years
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 250ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-330: Deferred for following: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate. • legalized original valid CoPP • confirmation of dedicated manufacturing facility • choice of only one pack size • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm submit following documents:' • copy of DSL valid unto 14-10-2024 • notarized original valid Letter of Authorization/ Sole agency certificate. • Original legalized valid CoPP • confirmation of dedicated manufacturing facility • pack size 100ml • Generic Amoxy 150 LA Injection (Reg.#43594)	
Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.		
1699.	Name and address of Applicant	M/s Qualivet Pharma,

		Office address: 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24715 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No.23252367362)
	Brand Name +Dosage Form + Strength	Exabiopen Suspension for Injection
	Composition	Each ml contains: Benzyl Penicillin Procaine…200 IU Dihydrostreptomycin sulfate…250mg
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of CoPP dated 17-12-2020 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer. ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [X]	Provided only **12 months long term** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide legalized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since already submitted is scanned copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 250ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-330:	

	Deferred for following: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate. • legalized original valid CoPP • 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions • confirmation of dedicated manufacturing facility • choice of only one pack size • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm submit following documents:' • copy of DSL valid unto 14-10-2024 • notarized original valid Letter of Authorization/ Sole agency certificate. • Original legalized valid CoPP • 24Month Stability data is submitted as per Zone-IVa • confirmation of dedicated manufacturing facility • pack size 100ml • Generic is not confiremed but product is from reference country i.e Spain	
Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.		
1700.	Name and address of Applicant	M/s Samara Stores, 17 Qamar Market Unit No 7, Latifabad, Hyderabad, Pakistan
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18199 Dated 22-06-2022
	Fee including differential fee	**Rs : 75,000** Dated 22-06-2022
	Brand Name +Dosage Form + Strength	Imicarb Injection
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antiprotozoal
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml, 100ml
	International availability	N/A
	Me-too status	Durazol Injection (50ml and 100ml) of M/s Mylab (Pvt) Ltd. Bahawalpur. (Reg. No. 078204)
	Detail of certificates attached	➢ Scanned copy of Free Sale Certificate No. 011244 issued by minister of Agriculture and Minister of Environment Jordan declaring the free sale of applied product in country of origin Date of issuance: 25-11-2020 ➢ Original legalized GMP certificate No. 011240 dated 25-11-2020 issued by minister of Agriculture and Minister of Environment Jordan, with validity: 3 years. ➢ Letter of Authorization/Sole Agency Certificate between PLH and Applicant **is not provided**

	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 75,000/- for registration of generic drug. • Provide valid copy of DSL • Provide original legalized valid FSC since the already submitted is scanned copy. • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 50ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.

Decision of 331st meeting of RB	**Firm reply**
Differential fee Rs. 75,000/- for registration of generic drug.	Submitted fee Rs. 75,000/- dated Jan 29, 2024 Slip no. 348418736
valid copy of DSL	DSL valid upto 06-01-2029
original legalized valid FSC	Copy submitted, firm claim original already submitted.
Letter of Authorization/Sole Agency Certificate between PLH and Applicant	Copy submitted, firm claim original already submitted.
Choice of only one pack size	100ml

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1701.	Name and address of Applicant	M/s Samara Stores, 17 Qamar Market Unit No 7, Latifabad, Hyderabad, Pakistan
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18200 Dated 22-06-2022
	Fee including differential fee	**Rs : 75,000** Dated 14-06-2022
	Brand Name +Dosage Form + Strength	Tectin Injection
	Composition	Each ml contains: Ivermectin…10mg Methylparapen…1.8mg Propylparapen…0.2mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antiparasite
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10ml, 50ml, 100ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized Free Sale Certificate No. 005677 issued by minister of Agriculture and Minister of Environment Jordan declaring the free sale of applied product in country of origin Date of issuance: 01-07-2019

		➢ Original legalized GMP certificate No. 005672 dated 01-07-2019 issued by minister of Agriculture and Minister of Environment Jordan, with validity: 3 years. ➢ Letter of Authorization/Sole Agency Certificate between PLH and Applicant **is not provided**
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 75,000/- for registration of generic drug. • Provide valid copy of DSL • Provide original legalized valid GMP certificate since the already submitted is expired now but valid upon submission. • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Decision of 331st meeting of RB	**Firm reply**
Differential fee Rs. 75,000/- for registration of generic drug.	Submitted fee Rs. 75,000/- dated Jan 29, 2024 Slip no. 25988541151
valid copy of DSL	DSL valid upto 06-01-2029
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	Firm inform that as per FSC composition of active ingredient is as under: Each ml contains: Ivermectin…10mg Generic Ivomek 1% Injection (072618)
Letter of Authorization/Sole Agency Certificate between PLH and Applicant	Copy submitted, firm claim original already submitted.
Choice of only one pack size	100ml

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1702.	Name and address of Applicant	M/s Samara Stores, 17 Qamar Market Unit No 7, Latifabad, Hyderabad, Pakistan
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18198 Dated 22-06-2022
	Fee including differential fee	**Rs : 75,000** Dated 14-06-2022
	Brand Name +Dosage Form + Strength	Flunixvet Injection
	Composition	Each ml contains: Flunixin as Flunixin Meglumine…50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Non-narcotic, non-steroidal analgesic agent with anti-inflammatory and antipyretic activity
	Shelf life	3 years

	Demanded Price	Decontrolled
	Pack size	50ml, 100ml
	International availability	N/A
	Me-too status	Flunix Injection (50ml and 100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059125)
	Detail of certificates attached	➢ Original legalized Free Sale Certificate No. 011243 issued by minister of Agriculture and Minister of Environment Jordan declaring the free sale of applied product in country of origin Date of issuance: 25-11-2020 ➢ Original legalized GMP certificate No. 011481 dated 02-12-2020 issued by minister of Agriculture and Minister of Environment Jordan, with validity: 3 years. ➢ Letter of Authorization/Sole Agency Certificate between PLH and Applicant **is not provided**
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 75,000/- for registration of generic drug. • Provide valid copy of DSL • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 50ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.

Decision of 331st meeting of RB	**Firm reply**
Differential fee Rs. 75,000/- for registration of generic drug.	Submitted fee Rs. 75,000/- dated Jan 29, 2024 Slip no. 43459322572
valid copy of DSL	DSL valid upto 06-01-2029
Letter of Authorization/Sole Agency Certificate between PLH and Applicant	Copy submitted, firm claim original already submitted.
Choice of only one pack size	100ml

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1703.	Name and address of Applicant	M/s Samara Stores, 17 Qamar Market Unit No 7, Latifabad, Hyderabad, Pakistan
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate- Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18197 Dated 22-06-2022
	Fee including differential fee	**Rs : 75,000** Dated 14-06-2022
	Brand Name +Dosage Form + Strength	Albevet 10% Oral Suspension
	Composition	Each ml contains: Albendazole…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled

	Pack size	500ml, 1000ml
	International availability	N/A
	Me-too status	Bendol 10 Suspension of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113512)
	Detail of certificates attached	➢ Original legalized Free Sale Certificate No. 000961 issued by minister of Agriculture and Minister of Environment Jordan declaring the free sale of applied product in country of origin Date of issuance: 29-01-2020 ➢ Original legalized GMP certificate No. 000964 dated 29-01-2020 issued by minister of Agriculture and Minister of Environment Jordan, with validity: 3 years. ➢ Letter of Authorization/Sole Agency Certificate between PLH and Applicant **is not provided**
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 75,000/- for registration of generic drug. • Provide valid copy of DSL • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant
	Decision: Deferred for following: • **Differential fee Rs. 75,000/- for registration of generic drug.** • **valid copy of DSL** • **Letter of Authorization/Sole Agency Certificate between PLH and Applicant**	

Decision of 331st meeting of RB	**Firm reply**
Differential fee Rs. 75,000/- for registration of generic drug.	Submitted fee Rs. 75,000/- dated Jan 29, 2024 Slip no. 02846790685
valid copy of DSL	DSL valid upto 06-01-2029
Letter of Authorization/Sole Agency Certificate between PLH and Applicant	Copy submitted, firm claim original already submitted.

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1704.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of validity: **23-02-2028** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	Huang Gang Animal Medicine Factory of China Animal Husbandry Industry Co. Ltd. No. 395, Lukou Industrial, Huangzhou Industrial Area, huang Gang City, Hubei Province, China.
	Name and address of marketing authorization holder	Huang Gang Animal Medicine Factory of China Animal Husbandry Industry Co. Ltd. No. 395, Lukou Industrial, Huangzhou Industrial Area, huang Gang City, Hubei Province, China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 4411 Dated 24-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 24-04-2019
	Brand Name +Dosage Form + Strength	Tylvalosin Tartrate 20% Premix
	Composition	Each Gram Contains: Tylvalosin Tartrate…200mg
	Finished Product Specification	**The national standards for Veterinary drugs**

	Pharmacological Group	Macrolide antibiotic
	Shelf life	02 Years
	Demanded Price	N/A
	Pack size	100gm, 500gm, 1Kg, 5Kg and 20Kg
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	**Photocopy of Legalized GMP certificate: reference to file submitted in December 2019.** **Certificate No:** 000304 **Certified by:** Ministry of Agriculture/The Veterinary Department-Pharmacy & Drugs Control Division/ In The Hashemite Kingdom of Jordan. **Issued on:** 11/01/2017 **Original Legalized free sale certificate:** Certificate No: 191100B0/013124 Certified by: China Council for the promotion of International Trade China Chamber of International Commerce **Issued on**: 10-03-2019 **Letter of Authorization (Photocopy)** Arab Veterinary Industrial Co. "AVICO" P.O Box 150906 Amman 11115- Jordan & U.M. Enterprises, 18 C 3rd Floor Dolmen Estate Block-7, Shaheed e Millat Road, Karachi. Issued on: **12th of June, 2012**
	Remarks of the Evaluator [X]	• The submitted photocopy of letter of Authorization (LOA) and GMP certificate are expired now, but valid upon submission, Provide legalized valid original LOA and GMP certificate. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product specifications. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board.
	Decision of 322nd meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions	
	Updated status: The firm has submitted its reply dated 22-02-2023 and 07-08-2023 • Original legalized LOA for the applied product dated 11-11-2022, from Huang Gang Animal Medicine Factory of China Animal Husbandry Industry Co. Ltd. No. 395, Lukou Industrial, Huangzhou Industrial Area, huang Gang City, Hubei Province, China valid for 5 years • Originally legalized GMP certificate No. (2021) S.Y.GMP Z.Zi, No.17001 dated 05-08-2021, issued by Department of Agriculture and Rural Affairs of Hubei Province valid till 28-01-2026	

- Rs.7500/- vide challan No. 611886556467 for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Submitted 06 months accelerated and 24 months' real time stability studies data of three batches at zone IV-A conditions
- The applied formulation/drug is not already registered in Pakistan. The firm has submitted reference of **Aivlosin 17%** approved in Canada

The reference product for Tylvalosin tatrate 20% is Aivlosin 17% (Reference product Canada) both are the same products, the calculation method (of why **Aivlosin 17%** is same assay as **Tylvalosin Tartrate Premix 20%**):

Molecular weight of **Tartrate**: 150.09
Molecular weight of **Tylvalosin tartrate**: 1192.34002

$$\left(1 - \frac{150.09}{1192.34002}\right) \times 20\% \approx \mathbf{17\%}$$

which means:
Assay of Tylvalosin tartrate premix 20% ≈ Assay of Aivlosin 17% (Tylvalosin 17%)

Decision M-331:
The registration Board after detail delebrations decided to defer the case for International reference of applied formulation as in Canada it is available for only swine use and not for poultry and the applicant's target specie is poultry.

Firm reply:
Importer submit reference from EMA which shows centralized approval of Tylvalosin with Brand name Aivlosin showing indication in Chickens,Turkeys with following strengths:

EU Number	Invented name	Strength	Pharmaceutical Form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal Period
EU/2/04/044/001	Aivlosin	42.5 mg/g	Premix for medicated feeding stuff	Pigs	In-feed use	Aluminium foil laminated bags	42.5 mg/g	20 kg	Meat and offal 2 days
EU/2/04/044/002	Aivlosin	42.5 mg/g	Premix for medicated feeding stuff	Pigs	In-feed use	Aluminium foil laminated bags	42.5 mg/g	5 kg	Meat and offal 2 days
EU/2/04/044/009	Aivlosin	625 mg/g	Granules for use in drinking water	Pigs	In drinking water use	Aluminium foil laminated sachet	625 mg/g	40 g	Meat and offal: 2 days
EU/2/04/044/010	Aivlosin	625 mg/g	Granules for use in drinking water	Pigs	In drinking water use	Aluminium foil laminated sachet	625 mg/g	160 g	Meat and offal: 2 days
EU/2/04/044/012	Aivlosin	625 mg/g	Granules for use in drinking water	Pheasant	In drinking water use	Aluminium foil laminated sachet	625 mg/g	40 g	Meat and offal: 2 days
EU/2/04/044/013	Aivlosin	42.5 mg/g	Oral powder	Pigs	In-feed use	aluminium foil/polyester laminated bag	42.5 mg/g	500 g	Meat and offal: 2 days
EU/2/04/044/014	Aivolsin	625 mg/g	Granules for use in drinking water	Pheasant	In drinking water use	Aluminium foil laminated sachet	625 mg/g	400 g	Meat and offal: 2 days
EU/2/04/044/017	Aivlosin	625 mg/g	Granules for use in drinking water	Pigs	In drinking water use	Aluminium foil laminated sachet	625 mg/g	400 g	Meat and offal: 2 days

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EU/2/04/044/018	Aivlosin	625 mg/g	Granules for use in drinking water	Chickens and turkeys	In drinking water use	Aluminium foil laminated sachet	625 mg/g	40 g	Meat and offal:2 days Eggs: zero days (chickens) Turkeys: Not authorised for laying birds.

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1705.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi

		Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name and address of marketing authorization holder	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12863 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Melen-Pro Oral Powder
	Composition	Each gram contains: Melengestrol Acetate…0.22mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm, 5000gm, 10000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Originally legalized COPP No. M2015795 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea. ➢ Original legalized letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product.
	Remarks of the Evaluator [X]	Firm has provided 24-month real time stability studies data of three batches at conditions **30ºC, 60% RH**. **Target species:** Heifer **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.

Decision 334:
Deferred for following:

- Choice of only one pack size/ fill volume
- evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.

Firm reply is as under:

Decision of 334th meeting of RB	Firm Reply
Choice of only one pack size/ fill volume	Since product is oral powder hence the one pack size policy is not applicable here.
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)	Not available

	alongwith registration number, brand name and name of firm	
	Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.	Firm has submitted Real time 24 months and accelerated 6 months stability data as per zone-iva.

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

1706.	Name and address of Applicant	M/s ZS Biotech, **Head office address**: 50-C, Madina Block, Awan Town, Multan Road, Lahore, Pakistan. **Warehouse address:** 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore.
	Detail of Drug Sale License	Name: M/s ZS Biotech Address: House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore. **Validity: 20-01-2024.** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Farmabase Saude Animal Ltda., Av. Emilio Marconato, n 1000-Jaguariuna, Brazil
	Name and address of marketing authorization holder	M/s Farmabase Saude Animal Ltda., Av. Emilio Marconato, n 1000- Jaguariuna, Brazil
	Name of exporting country	Brazil
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 15262 Dated 02-06-2021
	Fee including differential fee	Rs : 1,50,000 Dated 28-05-2021
	Brand Name +Dosage Form + Strength	Farmaxilin 50 Powder
	Composition	Each gram contains: Amoxicillin (as Amoxicillin trihydrate)…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	200gram sachet
	International availability	N/A
	Me-too status	Amocillin 50% Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.112326)
	Detail of certificates attached	• Scanned copy of FSC dated 02-05-2018 issued by the Ministry of Agriculture, Livestock, and Food Supply Livestock confirms free sale status of the product in country of origin. • Scanned copy of GMP Certificate dated 18-01-2023 issued by Ministry of Agriculture life stock and supply, Brazil. **(Does not cover the scope of penicillin production line.)** • Copy of legalized distribution agreement made on 13-06-2018 between the applicant and product license holder is provided. Validity: 36 Months
	Remarks of the Evaluator [x]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Submit legalized original valid FSC, since the already submitted scanned copy is ***expired now but valid upon submission.***

		• Submit legalized original valid relevant GMP certificate; covering the scope of **penicillin production lines.** • Confirmation of dedicated/ self-contained manufacturing facility • Provide notarized original valid distribution agreement between product license holder and distributor, since already submitted photocopy is **expired now but valid upon submission.**
	Decision of 330th meeting: Deferred for following: • legalized original valid FSC • legalized original valid GMP certificate covering the scope of penicillin production lines. • confirmation of dedicated/self-contained manufacturing facility • valid notarized original letter of authorization (LOA)/ distribution agreement The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted its reply dated 05-10-2023 • Copy of DSL valid till 20-01-2024 • Scanned copy of Legalized FSC dated 25-06-2021 • Copy of Legalized GMP certificate dated 18-01-2023. • Copy of legalized distribution agreement between product license holder and distributor • Clarification letter from the manufacture and declaration letter issued by Federal Superintendence of Agriculture, Livestock and Supply in the state of Sao Paulo, Brazil confirming that the manufacture has a segregated area for production of pesticides and penicillin.	
	Decision 331: Deferred for confirmation of dedicated facility for production of penicillin products. **Firm reply:** Firm submitted documents from manufacturer Abroad which shows that they have segregated area for production of penicillin.	
Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.		
1707.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2027. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24091 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 965127188165)
	Brand Name +Dosage Form + Strength	Oksimed Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100gm, 250gm, 500gm, 1000gm and 5000gm

	International availability	N/A
	Me-too status	Oxyveto-50 S Soluble Powder of M/s Orient Traders International, Karachi. (Reg. No. 049545)
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [x]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted **scanned copy is expired now but valid upon submission.** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • **Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg** is mentioned on Form 5A while **Oxytetracycline HCl…500mg** is mentioned on FSC; clarification regarding the applied formulation is required. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding the applied formulation since Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg is mentioned on Form 5A while Oxytetracycline HCl…500mg is mentioned on FSC	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.

	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted
	Decision: Approved. The firm shall submit fee Rs. 300,000/- for change in finished product specifications/salt form correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1708.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Idol Ilac Dolum San. Ve Tic.A.S. Davutpasa Cad. Cebealibey Sok. No: 20 34010 Zeytinburnu/Istanbul
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24086 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 4197476974)
	Brand Name +Dosage Form + Strength	Tilotarmed 20% Solution for Injection
	Composition	Each ml Contains: Tylosin Tartrate Eq. to Tylosin Base…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Tylox-20 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113562)
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S0212/2020 dated 16.03.2020 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Tilomed-E 30% Solution for Injection)** Validity: 17-07-2022 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted scanned copy is **expired now but valid upon submission.** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha***

		Road Faisalabad." while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted

Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1709.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Idol Ilac Dolum San. Ve Tic.A.S. Davutpasa Cad. Cebealibey Sok. No: 20 34010 Zeytinburnu/Istanbul
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24088 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 9580364966)
	Brand Name +Dosage Form + Strength	Tilomed-E 30% Solution for Injection
	Composition	Each ml contains: Tilmicosin Phosphate Eq. to Tilmicosin Base…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled

	Pack size	100ml
	International availability	N/A
	Me-too status	Mico Sol Injection (100ml) of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 080150)
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Originally legalized GMP certificate No. GMP/TR/V/YI/S0212/2020 dated 16.03.2020 certified by Ministry of Agriculture and Forestry Turkey. Validity: 17-07-2022 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted

Decision: Approved. The firm shall submit fee Rs. 7500- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1710.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.

		Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24089 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 476694961)
	Brand Name +Dosage Form + Strength	Medicatay Water Soluble granules
	Composition	Each gram Contains: Tylosin Tartrate Eq. to Tylosin Base…1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	22gm, 55gm, 110gm, 100gm, 500gm, 550gm, 1000gm, 1100gm
	International availability	N/A
	Me-too status	Tylo Tartrate-100 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113430)
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Originally legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate.

		III. Legalized FSC
	valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
	clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.
	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted
	Decision: Approved. The firm shall submit fee Rs. 7500- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1711.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24087 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 43956898)
	Brand Name +Dosage Form + Strength	Tilomed 30% Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate Eq. to Tilmicosin Base…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	70 x 250ml, 50 x 500ml, 10 x 1000ml bottles, 3 x 5000ml drum
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.

<table>
<tr><td></td><td>Remarks of the Evaluator [X]</td><td>Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions.
Shortcomings:
• Provide copy of valid DSL
• Provide valid legalized original GMP certificate, since the already submitted is expired now but valid upon submission
• Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy.
• Address of the firm mentioned on DSL is "Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad." while "Commercial-6, Block A, Kazimabad, Model Colony, Karachi" is mentioned on form-5A, clarify.
• In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td></td><td colspan="2">Firm reply is as under:
<table>
<tr><th>Decision of 330th meeting of RB</th><th>Firm reply</th></tr>
<tr><td>copy of valid DSL</td><td>Submitted</td></tr>
<tr><td>valid legalized original GMP certificate</td><td>Submitted
Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents:
I. Fee Rs. 150,000/-
II. Legalized GMP Certificate.
III. Legalized FSC</td></tr>
<tr><td>valid notarized original letter of authorization (LOA)/ distribution agreement</td><td>Submitted</td></tr>
<tr><td>clarification regarding address of the applicant mentioned on DSL, since "Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad." Is mentioned on DSL while "Commercial-6, Block A, Kazimabad, Model Colony, Karachi is mentioned on form-5A</td><td>Submitted and request for processing of case as per DSL address.</td></tr>
<tr><td>label in accordance with The Drugs (Labeling and Packing) Rules, 1986</td><td>Submitted</td></tr>
<tr><td>evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td><td>Submitted
Micowan 300 Injection (Reg#099377)</td></tr>
</table>
Decision: Approved. The firm shall submit fee Rs. 7500- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.</td></tr>
<tr><td>1712.</td><td>Name and address of Applicant</td><td>M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan</td></tr>
<tr><td></td><td>Detail of Drug Sale License</td><td>Name: M/s Unicare Enterprises
Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.
Validity: 10-04-2022.
Status: License to sell drugs as a distributor (Form No.11).</td></tr>
<tr><td></td><td>Name and address of manufacturer</td><td>Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey</td></tr>
<tr><td></td><td>Name and address of marketing authorization holder</td><td>Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey</td></tr>
</table>

	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24093 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 5459799264)
	Brand Name +Dosage Form + Strength	Mediquinol 20% Oral Solution
	Composition	Each ml contains: Enrofloxacin…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml
	International availability	N/A
	Me-too status	Bovicin-20 Oral Solution of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.112149)
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [x]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is	Submitted and request for processing of case as per DSL address.

	mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	
	label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted
	Decision: Approved. The firm shall submit fee Rs. 7500- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
1713.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24092 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 5344055462)
	Brand Name +Dosage Form + Strength	NS-Med 50% Oral Solution Powder
	Composition	Each gram Contains: Neomycin Sulphate 715mg Eq. to Neomycin Base…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	20gm, 100gm, 500gm, 1000gm, 2500gm
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha***

		Road Faisalabad." while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted
evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	Submitted Neomix 325 Soluble (Reg.# 046647)

Decision: Approved. The firm shall submit fee Rs. 300,000- for change in finished product specifications/salt form correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

1714.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24090 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 39669651)
	Brand Name +Dosage Form + Strength	Tetraklor Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline Base…600mg

Finished Product Specification	Inhouse
Pharmacological Group	Antibiotic
Shelf life	36 months
Demanded Price	Decontrolled
Pack size	20gm, 100gm, 500gm, 1000gm, 2500gm
International availability	N/A
Me-too status	**Could not be confirmed in the applied strength**
Detail of certificates attached	➢ Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 ➢ Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • **Chlortetracycline Base…600mg/gram** is mentioned on Form 5A while **Chlortetracycline HCl…600mg/gram** is mentioned on FSC; clarification regarding the applied formulation is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Firm reply is as under:

Decision of 330th meeting of RB	**Firm reply**
copy of valid DSL	Submitted
valid legalized original GMP certificate	Submitted Showing only name of manufacturer is changed from Medicavet to Class Pharma. Firm have submitted following documents: I. Fee Rs. 150,000/- II. Legalized GMP Certificate. III. Legalized FSC
valid notarized original letter of authorization (LOA)/ distribution agreement	Submitted
clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A	Submitted and request for processing of case as per DSL address.
label in accordance with The Drugs (Labeling and Packing) Rules, 1986	Submitted

	clarification regarding the applied formulation since Chlortetracycline Base…600mg/gram is mentioned on Form 5A while Chlortetracycline HCl…600mg/gram is mentioned on FSC	submitted
	evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	Not Submitted

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

1715.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 30039 Dated 10-11-2020
	Fee including differential fee	Rs : 100,000 Dated 10-11-2020
	Brand Name +Dosage Form + Strength	Amoxi 15% Injection 100ml
	Composition	Each ml Contains: Amoxicillin…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Vime-Amox 15% La Veterinary Liquid Injection (100ml) of M/s Al-Asar Enterprises, Multan. (Reg. No. 094478)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **(Scope of submitted GMP certificate** Validity: 26-01-2021 **does not cover penicillin injectable)** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC.

		• The submitted copy of GMP certificate is **expired now, but valid upon submission; Moreover,** Scope of submitted GMP certificate does not cover penicillin injectable Provide legalized valid original relevant GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.

Decision of 326th meeting of RB	**Firm reply**
legalized original valid FSC	Submitted
legalized original valid relevant GMP certificate	Submitted
Label in accordance with The Drugs (Labelling and Packing) Rules, 1986.	Submitted

Decision: Approved. The firm shall submit fee Rs. 300,000- for change in finished product specifications/salt form correction prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.

Agenda of Deputy Director (PE&R) (Mr. Adil Saeed)

1716	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Apsis Pharmaceuticals Eminabad road Khan payara, 1.3KM GT Road, Gujranwala. (DML No. 000855)**
	Name, address of Manufacturing site.	M/s Apsis Pharmaceuticals Eminabad road Khan payara, 1.3KM GT Road, Gujranwala. (DML No. 000855)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33449, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 565477162535
	The proposed proprietary name / brand name	**BATALASOL 5% IV Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml contains; Dextrose anhydrous……5gm
	Pharmacotherapeutic Group of (API)	Glucose Infusion
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	5% GLUCOSE INTRAVENOUS INFUSION SOLUTION MHRA Approved.
	For generic drugs (me-too status)	Dexsol 5% IV Infusion

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Water loss studies data has not been submitted.	
2	3.2.P.8	Batch sizes are given in litres, batch size in number of units is required.	

Decision: The board was appraised that deficiencies are communicated to the firm. Reply from the firm is awaited. The board deferred the case for submission of reply of communicated deficiencies.

1717	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-KM, Lahore-Gujranwala road, Khori, District Sheikhupura. (DML No. 000805)**

	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-KM, Lahore-Gujranwala road, Khori, District Sheikhupura. (DML No. 000805)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5488, Dt. 27.02.2023
	Details of fee submitted	**PKR 30,000/- : Slip No. 96932318813**
	The proposed proprietary name / brand name	**SUGAMMADEX IV Injection 200mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule contains; Sugammadex as sodium……..200mg
	Pharmacotherapeutic Group of (API)	Antidotes ATC Code: V03AB35
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUGAMMADEX 100 MG/ML SOLUTION FOR INJECTION MHRA Approved.
	For generic drugs (me-too status)	Could not be verified

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	1.5.2	The label applied is Sugammadex sodium…200mg. Innovator product has label of Sugammadex as sodium 200mg. Correction of label along with requisite fee is required.	The firm vide letter No. BPL/DRAP/24/419 dated 30.05.2024 has submitted their response. Fee of Rs. 7500/- vide slip No. 3984138750 us submitted for correction of label.
2	1.5.8	It is mentioned that there is no local reference of the applied product, so it's a new drug product. Fee submitted is Rs. 30,000/-. Differential fee is required as application is for a New Drug Product.	Differential fee of Rs. 45000/- vide slip No. 91201592970 is submitted.
3	-	AD Attested invoice or clearance certificate of drug substance is required.	Submitted. AD attested invoice of Sugammadex sodium Batch No. SDSSS011
4	3.2.P.8	Copies of executed (Filled) BMR of trial batches are required.	Submitted
5	3.2.P.5 & 3.2.P.8	Why liquid particle count test is not made part of testing of drug product and part of stability testing? Further why sterility testing is not part of stability studies. Clarify.	The firm has stated that these tests were performed but were of made part of report, now they are made part of stability report.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1718	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-KM, Lahore-Gujranwala road, Khori, District Sheikhupura. (DML No. 000805)**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-KM, Lahore-Gujranwala road, Khori, District Sheikhupura. (DML No. 000805)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31582, Dt. 03.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 64620178749
	The proposed proprietary name / brand name	**Noradrenaline 4mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule contains; Noradrenaline……4mg
	Pharmacotherapeutic Group of (API)	Adrenergic and dopaminergic agents ATC Code: C01CA03
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for solution for Infusion MHRA Approved.
	For generic drugs (me-too status)	Epinor Injection

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	1.5.2	The label applied is Noradrenaline…4mg. Innovator product has label of Noradrenaline as bitartarate…4mg Correction of label along with requisite fee is required.	The firm vide letter No. BPL/DRAP/24/421 dated 30.05.2024 has submitted their response. **Fee of Rs. 7500/- vide slip No. 832292235365 is submitted for correction of label.**
2	-	AD Attested invoice or clearance certificate of drug substance is required.	Submitted. AD attested invoice of Noradrenaline Bitartrate 50g Batch No. A210602
3	3.2.P.5	The USP monograph mentions use of isoproterenol in assay of Norepinephrine Bitartrate Injection, as per your provided method of analysis isoproterenol is not used. Justify this deviation from pharmacopoeial method.	The firm has submitted copies of chromatograms indicating use of isoproterenol in system suitability run.
4	3.2.P.8	Why liquid particle count & sterility testing is not made part o of stability testing?	The firm has stated that these tests were performed but were of made part of report, now they are made part of stability report.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1719	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Briell Pharmaceuticals (Pvt.) Ltd., 538-C Sundar Industrial Estate Multan Road Lahore. (DML No. 000862)**
	Name, address of Manufacturing site.	M/s Briell Pharmaceuticals (Pvt.) Ltd., 538-C Sundar Industrial Estate Multan Road Lahore. (DML No. 000862)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34816, Dt. 01.12.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 25770392886
	The proposed proprietary name / brand name	**Diliner 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Duloxetine (HCl) EC pellets 17% eq. to Duloxetine…….20mg
	Pharmacotherapeutic Group of (API)	Other antidepressants ATC Code: N06AX21
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DULOXETINE 20 MG GASTRO-RESISTANT CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Zenber 20mg Capsule M/s The Searle company.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	
2	3.2.P.5.3	Under heading system suitability, general definition of system suitability is given. Detailed method of performing system suitability is required. Further as per chromatograms submitted for system suitability run, it appears that USP method of system suitability is not followed (use of alpha naphthol and related compound F). Please justify this deviation and provide evidence that USP allows such deviation.	

Decision: Deferred for the submission of reply of the communicated deficiencies

1720.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CITI Pharma (Pvt.) Ltd. 3KM Head Balloki Road, Phool Nagar, Distt Kasur. (DML No. 000512)**
	Name, address of Manufacturing site.	M/s CITI Pharma (Pvt.) Ltd. 3KM Head Balloki Road, Phool Nagar, Distt Kasur. (DML No. 000512)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 47, Dt. 01.01.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 10344361425
	The proposed proprietary name / brand name	**ASKPROL-D Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Diclofenac sodium……..50mg Paracetamol……500mg
	Pharmacotherapeutic Group of (API)	Antipyretic, Anti-inflammatory & Analgesic
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Could not be verified.**
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Verifiable RRA reference of applied formulation is required.	
2	-	Copy of GMP certificate of drug Substance (Diclofenac sodium) is required.	
3	-	Copy of AD attested invoice of Diclofenac sodium or its clearance certificate is required.	
4	1.5.6	Finished product specifications claimed are USP Specifications, please submit copy of USP monograph of the product.	
5	3.2.P.2	The manufacturer of reference product Clofains 500mg/50mg Tablet is mentioned as Exphar s.a. Belgium. The product Clofains tablet is not present in registered drug list of Belgian Drug Authority. Please clarify the origin of reference product.	
6	3.2.P.2.2	The comparative dissolution is only performed in water. As per ICH guidelines, its required to be performed at 3 physiological pH values. Please Justify.	
7	3.2.P.8	• Size of stability batches is not mentioned. • Date of manufacturing of batches is 12.2021 and Initiation of stability is dated as 09.2021. Clarification is required. Copies of executed BMRs of stability batches are not submitted.	

Decision: Deferred for the submission of reply of the communicated deficiencies

1721	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 367, Dt. 04.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 627860516661
	The proposed proprietary name / brand name	**TENEPTIN 20mg Tablets**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Tenegliptin hydrobromide hydrate eq to Tenegliptin…….20mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) inhibitors ATC Code: A10BH08
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tenelia 20mg tablets PMDA Japan Approved.
	For generic drugs (me-too status)	Tenliptin Tablets 20mg M/s Indus Pharma

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1722	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34954, Dt. 02.12.2022
	Details of fee submitted	PKR 75,000/- : Slip No. 4911166382
	The proposed proprietary name / brand name	**CALCIFEROL 7.5mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Cholecalciferol……..300,000IU
	Pharmacotherapeutic Group of (API)	Vitamin D Analogue.
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	1's 1's x 5
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarenel® Injection AIFA Italy Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply

1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Complete stability data submitted vide letter No. GP/OL/R145/24 dated 09.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1723	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32889, Dt. 16.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 2999587089
	The proposed proprietary name / brand name	**APIXABAN 2.5MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….2.5mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	10’s, 14’s, 30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APIXABAN ACCORD 2.5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 2.5mg Tablets, M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Submitted vide letter No. nil dated 20.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1724	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31781, Dt. 04.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 002006052
	The proposed proprietary name / brand name	**APIXABAN 5MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….5mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	10's, 14's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APIXABAN ACCORD 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 5mg Tablets, M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Submitted vide letter No. nil dated 20.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1725	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 841, Dt. 10.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 031770241
	The proposed proprietary name / brand name	**DICLOFENAC Sodium R 75mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Diclofenac sodium ……..75mg (25mg as gastro-resistant pellets(24%) and 50mg prolonged release pellets(33%))
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB05

	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	10's,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Motifene 75 mg Capsules MHRA Approved.
	For generic drugs (me-too status)	Dicloyan-S 75mg Capsules, M/s Roryan

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Submitted vide letter No nil dated 21.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1726	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 471, Dt. 05.01.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 79685503574
	The proposed proprietary name / brand name	**OMEDIC 75mg/20mg Modified Release Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Diclofenac sodium ……..75mg (25mg as gastro-resistant pellets(24%) and 50mg prolonged release pellets(33%)) Omeprazole (as 22.5% EC pellets)……..20mg
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances diclofenac, combinations ATC Code: M01AB55
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	10's,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diclopram 75 mg/ 20 mg modified-release hard capsules (diclofenac sodium and omeprazole) - PL 33616/0002; UK/H/5465/001/DC MHRA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply

1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Submitted vide letter No. nil dated 21.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1727	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 45, Dt. 02.01.2020
	Details of fee submitted	PKR 75,000/- : Slip No. 89192944
	The proposed proprietary name / brand name	**GLOBICEFTA 2.5g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftazidime pentahydrate eq. to Ceftazidime….2g Avibactam sodium eq to Avibactum……0.5g
	Pharmacotherapeutic Group of (API)	Ceftazidime and beta-lactamase inhibitor ATC Code: J01DD52
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	1’s,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZAVICEFTA 2 G/0.5 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Stability studies data of 3 months is submitted. Data of 6 months is required.	Submitted vide letter No. nil dated 20.05.2024

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1728.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceutical Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi. (DML No. 000597)**

	Name, address of Manufacturing site.	M/s High-Q Pharmaceutical Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi. (DML No. 000597)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32813, Dt. 15.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 498245511
	The proposed proprietary name / brand name	**UFRIM 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram Oxalate eq. to. Escitalopram …..5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	10's & 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Cipralex 5mg Film coated tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5.3	In Analytical procedures and verification information summaries, infront of system suitability solution concentration it is mentioned that "sample = standard". As per USP monograph system suitability solution is 6.4mcg/ml Escitalopram oxalate RS and 1mcg/ml USP Citalopram Related Compound C RS in mobile phase. Please clarify what is meant by system suitability solution being sample = standard and also justify how it is comparable to USP system suitability solution.	The firm vide letter No. HQ/QUE/UFR-05/2024 dated 14.05.2024 has submitted their response. The firm has stated that it was a typographic mistake, in system suitability it is "system suitability solution + standard solution" Revised testing method is submitted.
2	3.2.P.5	Method of dissolution is not given in detail and it is not clarified which test will be used (either Test 1 or Test 2. Please clarify.	The firm has stated that USP Dissolution Test 2 is used.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1729.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceutical Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi. (DML No. 000597)**

	Name, address of Manufacturing site.	M/s High-Q Pharmaceutical Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi. (DML No. 000597)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5356, Dt. 24.02.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 15581550
	The proposed proprietary name / brand name	**DAYFORT PLUS 2.5g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftazidime pentahydrate eq. to Ceftazidime….2g Avibactam sodium eq to Avibactum……0.5g
	Pharmacotherapeutic Group of (API)	Ceftazidime and beta-lactamase inhibitor ATC Code: J01DD52
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZAVICEFTA 2 G/0.5 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	Zavicefta 2.5g IV Injection M/s Pfizer.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1730.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33454, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 365771579
	The proposed proprietary name / brand name	**CIPRAM 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram as oxalate……..5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors

		ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 5mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	
2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	
3	3.2.P.8	Stability Studies data of 3 months is submitted. Data of 6 months is required.	

Decision: Deferred for the submission of reply of the communicated deficiencies

1731.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33453, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 06734487
	The proposed proprietary name / brand name	**CIPRAM 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram as oxalate……..10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 10MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 10mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	Submitted vide letter No. IP/DR/038 dated 24.05.2024.

2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	The firm has not submitted any justification of deviation from USP monograph. Chromatograms of system suitability run are submitted wherein peak of Compound C is not present. The firm has submitted partial reply.

Decision: The Board deferred the case for submission of complete reply with justification for deviation from official monograph in assay of drug product.

1732.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt.) Ltd. 112/10 Quaid e Azam Industrial Area Kot Lakhpat Lahore. (DML No. 000150)**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt.) Ltd. 112/10 Quaid e Azam Industrial Area Kot Lakhpat Lahore. (DML No. 000150)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34711, Dt. 30.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 472087262
	The proposed proprietary name / brand name	**RESPRIDE 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Risperidone……2mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics ATC Code: N05AX08
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	For generic drugs (me-too status)	RISP 2mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1733.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals (Pvt.) Ltd. 112/10 Quaid e Azam Industrial Area Kot Lakhpat Lahore. (DML No. 000150)**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals (Pvt.) Ltd. 112/10 Quaid e Azam Industrial Area Kot Lakhpat Lahore. (DML No. 000150)

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 34712, Dt. 30.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 0962428284
	The proposed proprietary name / brand name	**RESPRIDE 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Risperidone……4mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics ATC Code: N05AX08
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	For generic drugs (me-too status)	RISPERIGET 4mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1734.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1856, Dt. 19.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 284819137127 PKR 45,000/- Slip no. 95125517
	The proposed proprietary name / brand name	**ALERNIL 2.5mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains; Bilastine……2.5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX29

	Reference to Finished product specifications	**Innovators Specifications**
	Proposed Pack size	60ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ILAXTEN 2.5MG/ML ORAL SOLUTION MHRA Approved.
	For generic drugs (me-too status)	**NA**

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	The batch size mentioned in stability data sheets is 1L. As per bill of material in BMR, volume per bottle is 100ml, It makes total batch size of 10 units each. Justify how this small batch can be used in stability studies over whole proposed shelf life.	The firm vide letter No. RA/DRAP/708/2024 dated 24.05.2024 has stated that stability batch size is 10 units, One bottle was consumed in initial testing. 6 were placed on real time stability. 2 were placed on accelerated stability study.

Decision: The board deferred the case for clarification of the firm that how batch of 1 litre was manufactured and in which facility. Further the firm should justify how stability of such a small batch will represent the stability of commercial scale batches.

1735.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1857, Dt. 19.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 51893095835 PKR 45,000/- Slip no. 90661792739
	The proposed proprietary name / brand name	**ALERNIL 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Bilastine……20mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX29
	Reference to Finished product specifications	**Innovators Specifications**
	Proposed Pack size	10's. 20's, 30's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	ILAXTEN 20mg Tabletss MHRA Approved.
	For generic drugs (me-too status)	**NA**

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1736.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate Hattar. (DML No. 000363)**
	Name, address of Manufacturing site.	M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate Hattar. (DML No. 000363)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1969, Dt. 20.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 88427038923
	The proposed proprietary name / brand name	**ETIPRO 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains Omeprazole…….40mg Sodium bicarbonate….1680mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC01
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zegerid Sachet USFDA Approved.
	For generic drugs (me-too status)	Risek Insta 40mg Sachet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Stability studies data of 3 months is submitted. Stability data of 6 months is required.	The firm has submitted their response vide letter No. nil dated 27.05.2024 Stability data has been submitted.
2	-	At the time of submission of application (20.01.2023), the title of firm was M/s ICI Pakistan Limited. The firm had applied for change of title to Lucky Core Industries Limited to licensing division on 27.12.2022. The title of firm was changed on 15.02.2023.	Fee of Rs. 30,000/- vide slip No. 8944537144 has been submitted for pre-registration variation

		Fee for pre-registration variation will be required for change of title of firm in application.	

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1737.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Ltd, 7- Jail Road, Quetta. (DML No. 000028)**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Ltd, 7- Jail Road, Quetta. (DML No. 000028)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2736, Dt. 31.01.2023
	Details of fee submitted	PKR 75,000/- : Slip No.679526651
	The proposed proprietary name / brand name	**BEMPEDOIC ACID 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Bempedoic acid……180mg
	Pharmacotherapeutic Group of (API)	Lipid Lowering agent ATC Code: C10AX15
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXLETOL 180mg Tablet USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1738.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)**
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32890, Dt. 16.11.2022

	Details of fee submitted	PKR 30,000/- : Slip No. 22599413421
	The proposed proprietary name / brand name	**PD-CEF 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium equivalent to ceftriaxone..250mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Rocephin 250mg IV by M/s Martin Dow Quetta.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5.3	The specifications claimed are USP specifications. As per USP method of analysis, a resolution solution is required to be prepared and used to ensure that system resolution is suitable for the assay or not. In submitted method of analysis, no such thing is mentioned. Further the column, mobile phase and wavelength, used in your test method is different than the one recommended by USP. Please justify these deviations from USP method of analysis and how system suitability can be ensured with such changes and not using the resolution solution.	The firm vide letter No. PDHL/D&RA/24/426 dated 25.05.2024 has submitted their response. The firm has stated that now they have revised their testing method to comply with USP and E-isomer will be used to assess system suitability.
2.	3.2.P.2 & 3.2.P.5	No method for sterility testing of the finished product is submitted. Further sterility testing report is neither part of executed BMR nor of the product test and analysis. Justify.	Method/SOP for sterility testing is submitted. The firm has attached Sterility report and BET test reports with the BMR and resubmitted them.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1739.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)**
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32981, Dt. 16.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 41891488
	The proposed proprietary name / brand name	**PD-CEF 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium equivalent to ceftriaxone……..500mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Rocephin 500mg IV by M/s Martin Dow Quetta.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5.3	The specifications claimed are USP specifications. As per USP method of analysis, a resolution solution is required to be prepared and used to ensure that system resolution is suitable for the assay or not. In submitted method of analysis, no such thing is mentioned. Further the column, mobile phase and wavelength, used in your test method is different than the one recommended by USP. Please justify these deviations from USP method of analysis and how system suitability can be ensured with such changes and not using the resolution solution.	The firm vide letter No. PDHL/D&RA/24/426 dated 25.05.2024 has submitted their response. The firm has stated that now they have revised their testing method to comply with USP and E-isomer will be used to assess system suitability.
2.	3.2.P.2 & 3.2.P.5	No method for sterility testing of the finished product is submitted. Further sterility testing report is neither part of executed BMR nor of the product test and analysis. Justify.	Method/SOP for sterility testing is submitted. The firm has attached Sterility report and BET test reports with the BMR and resubmitted them.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1740.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)**
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31338, Dt. 02.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 665736898890
	The proposed proprietary name / brand name	**PD-CEF 1gm IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium equivalent to ceftriaxone……..1gm
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Rocephin 1g IM by M/s Martin Dow Karachi.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5.3	The specifications claimed are USP specifications. As per USP method of analysis, a resolution solution is required to be prepared and used to ensure that system resolution is suitable for the assay or not. In submitted method of analysis, no such thing is mentioned. Further the column, mobile phase and wavelength, used in your test method is different than the one recommended by USP. Please justify these deviations from USP method of analysis and how system suitability can be ensured with such changes and not using the resolution solution.	The firm vide letter No. PDHL/D&RA/24/426 dated 25.05.2024 has submitted their response. The firm has stated that now they have revised their testing method to comply with USP and E-isomer will be used to assess system suitability.
2.	3.2.P.2 & 3.2.P.5	No method for sterility testing of the finished product is submitted. Further sterility testing report is neither part of executed BMR nor of the product test and analysis. Justify.	Method/SOP for sterility testing is submitted. The firm has attached Sterility report and BET test reports with the BMR and resubmitted them.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1741.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)**

	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt.) Ltd. 9.5KM, Sheikhupura Road, Lahore. (DML No. 000039)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31337, Dt. 02.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 74354840229
	The proposed proprietary name / brand name	**PD-CEF 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium equivalent to ceftriaxone……..2gm
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Oxidil 2gm IV injection.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5.3	The specifications claimed are USP specifications. As per USP method of analysis, a resolution solution is required to be prepared and used to ensure that system resolution is suitable for the assay or not. In submitted method of analysis, no such thing is mentioned. Further the column, mobile phase and wavelength, used in your test method is different than the one recommended by USP. Please justify these deviations from USP method of analysis and how system suitability can be ensured with such changes and not using the resolution solution.	The firm vide letter No. PDHL/D&RA/24/426 dated 25.05.2024 has submitted their response. The firm has stated that now they have revised their testing method to comply with USP and E-isomer will be used to assess system suitability.
2.	3.2.P.2 & 3.2.P.5	No method for sterility testing of the finished product is submitted. Further sterility testing report is neither part of executed BMR nor of the product test and analysis. Justify.	Method/SOP for sterility testing is submitted. The firm has attached Sterility report and BET test reports with the BMR and resubmitted them.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1742.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2388, Dt. 25.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No.785717727193
	The proposed proprietary name / brand name	**ESCADEP 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram oxalate eq. to Escitalopram…..20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	10's 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipralex 20mg Film coated tablet MHRA Approved.
	For generic drugs (me-too status)	Depsit 20mg Tablets M/s Genix Pharma.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5	Under the heading of system suitability tests, its mentioned that its done by calculating symmetry factor and RSD for 5 replicate injections of standard preparations. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted their response vide letter No. nil dated nil. The firm has stated that they have revised the method of analysis to comply with the USP monograph. But even in revised method there is no mentioning of Compound C for assessing system suitability.
2	-	Copy of clearance certificate or AD attested invoice of drug substance is required.	Firm has submitted clearance certificate of batch No. AE-084/22 cleared in 2023. Trial batches were manufactured by batch No. EO-108/20 in 2021 & 2022

Decision: The board deferred the case for submission of;

i. Clarification of submission of clearance of different batch of drug substance

ii. Justification of deviating from official monograph of drug product.

1743.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2387, Dt. 25.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No.634829387
	The proposed proprietary name / brand name	**ESCADEP 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram oxalate eq. to Escitalopram…..5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	10's 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipralex 5mg Film coated tablet MHRA Approved.
	For generic drugs (me-too status)	Depsit 5mg Tablets M/s Genix Pharma.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5	Under the heading of system suitability tests, its mentioned that its done by calculating symmetry factor and RSD for 5 replicate injections of standard preparations. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted their response vide letter No. nil dated nil. The firm has stated that they have revised the method of analysis to comply with the USP monograph. But even in revised method there is no mentioning of Compound C for assessing system suitability.
2	-	Copy of clearance certificate or AD attested invoice of drug substance is required.	Firm has submitted clearance certificate of batch No. AE-084/22 cleared in 2023. Trial batches were manufactured by batch No. EO-108/20 in 2021 & 2022

Decision: The board deferred the case for submission of;

iii. Clarification of submission of clearance of different batch of drug substance

i. Justification of deviating from official monograph of drug product.

1744.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swiss Pharmaceuticals (Pvt.) Ltd. A/159, SITE-II Super Highway Karachi. (DML No. 000438)**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals (Pvt.) Ltd. A/159, SITE-II Super Highway Karachi. (DML No. 000438)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 600, Dt. 06.01.2023
	Details of fee submitted	**PKR 10,000/- : Slip No. 778916726** **PKR 20,000/- Slip No. 1940385 dated 09.04.2020.** **Endorsed on 15.05.2020 (Old manual green slip)**
	The proposed proprietary name / brand name	**STRACEF 2g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Ceftriaxone sodium eq to Ceftriaxone….2g
	Pharmacotherapeutic Group of (API)	Third Generation Cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 2g Injection MHRA Approved.
	For generic drugs (me-too status)	Inocef 2000mg IV Injection M/s Barrett Hodgson Pakistan (Pvt) Ltd.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Initially application is dated 03.04.2020 nd fee of Rs. 20,000/- is endorsed over old application. Then application is submitted in DRAP on 06.01.2023 with Rs. 10,000/- differential fee. Please clarify why fee of old application dated 03.04.2020 is being attached with application dated 02.12.2022?	The firm has responded vide letter No. DRAP/P&EC/SWISS/03/23-05-22 dated 23.05.2024 wherein they have stated that they have again submitted fee of Rs. 20,000/- vide slip No. 0337339229
2	3.2.P.5	Chromatograms of system suitability run are required.	The firm has submitted chromatograms. E-isomer peak is at 16.236 RT and Ceftriaxone peak is at 11.748 RT. Having a resolution of 5.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1745.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt.) Ltd. L-20/B, Sector-22, F.B Industrial Area Karachi. (DML No. 000106)**

	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd. L-20/B, Sector-22, F.B Industrial Area Karachi (DML No. 000106)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31372, Dt. 02.11.2022
	Details of fee submitted	PKR 75,000/- : Slip No. 700629068
	The proposed proprietary name / brand name	**NEBIVOL-H 5/25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Nebivolol Hydrochloride eq. to Nebivolol…..5mg Hydrochlorothiazide…..25mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective, and thiazides ATC Code: C07BB12
	Reference to Finished product specifications	**Tabros Specifications**
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in following European countries; i. Bulgaria ii. Latvia iii. Hungary iv. Estonia Hypoloc Plus 5 mg / 25 mg film-coated tablets HPRA Ireland Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	Submitted vide letter No. tabros/DRAP/Nebivolol-H-5-25/05-24/05 dated 14.05.2024
2	3.2.P.5	Finished product specifications are claimed as Tabros Specifications, justification is required for claiming manufacturer specifications.	The firm has stated that they had previously applied Tabros' Specs as per routine of that time. Now they intend to change specifications to Innovator's Specifications. Fee for change of specifications is not submitted.

Decision: Approved innovator specifications. Letter shall be issued after submission of fee of Rs. 7500/-.

1746.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4218, Dt. 14.02.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 685535160
	The proposed proprietary name / brand name	**DEWA 40mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Drotaverine Hydrochloride…….40mg
	Pharmacotherapeutic Group of (API)	Papaverine and derivatives ATC Code: A03AD02
	Reference to Finished product specifications	**Innovator Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
	For generic drugs (me-too status)	No-Spa Tablet 40mg

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of GMP certificate of Drug substance manufacturer is required.	Submitted.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2741, Dt. 31.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 027397115
	The proposed proprietary name / brand name	**NEFO 2.5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol Hydrochloride eq to Nebivolol… 2.5mg

	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC Code: C07AB12
	Reference to Finished product specifications	**Innovator's Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nebivolol 2.5, 5 & 10mg Tablets - PL 44041/0050-52 MHRA Approved.
	For generic drugs (me-too status)	Nebix 2.5mg Tablet M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1748.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2742, Dt. 31.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 865341010
	The proposed proprietary name / brand name	**NEFO 5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol Hydrochloride eq to Nebivolol… 5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC Code: C07AB12
	Reference to Finished product specifications	**Innovator's Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nebivolol 2.5, 5 & 10mg Tablets - PL 44041/0050-52 MHRA Approved.
	For generic drugs (me-too status)	Nebix 5mg Tablet M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1749.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2743, Dt. 31.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 857358229383
	The proposed proprietary name / brand name	**NEFO 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol Hydrochloride eq to Nebivolol… 10mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC Code: C07AB12
	Reference to Finished product specifications	**Innovator's Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nebivolol 2.5, 5 & 10mg Tablets - PL 44041/0050-52 MHRA Approved.
	For generic drugs (me-too status)	Nebix 10mg Tablet M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1750.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Welmark Pharmaceuticals, Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar. (DML No. 000614)**
	Name, address of Manufacturing site.	M/s. Welmark Pharmaceuticals, Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar. (DML No. 000614)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1053, Dt. 12.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 18619529370

	The proposed proprietary name / brand name	**MYTAKRO 0.5mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Tacrolimus monohydrate eq. to Tacrolimus…….0.5mg
	Pharmacotherapeutic Group of (API)	Calcineurin inhibitors ATC Code: L04AD02
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Taliximun 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0015-7; UK/H/2178/01-03/DC MHRA Approved.
	For generic drugs (me-too status)	Tacgraf 0.5mg Capsule M/s CCL

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1751.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36509, Dt. 15.12.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 2583423990
	The proposed proprietary name / brand name	**APPIXO 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….2.5mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APIXABAN ACCORD 2.5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 2.5mg Tablets, M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of AD attested invoice or clearance certificate of drug substance is required.	Submitted
2	3.2.P.8	Copies of executed BMRs of trial batches are required.	Submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1752.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35147, Dt. 05.12.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 61708850
	The proposed proprietary name / brand name	**APPIXO 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….5mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APIXABAN ACCORD 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 5mg Tablets, M/s Highnoon

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of AD attested invoice or clearance certificate of drug substance is required.	Submitted
2	3.2.P.8	Copies of executed BMRs of trial batches are required.	Submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1753.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V Industrial Estate Hattar. (DML No. 000610)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3664, Dt. 08.02.2023
	Details of fee submitted	PKR 30,000/- : Slip No.823054221
	The proposed proprietary name / brand name	**ROSTA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium……5mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ropuido 5 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	Rolip 5mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of AD attested invoice or clearance certificate of drug substance is required.	Submitted
2	-	Copy of GMP certificate of drug substance manufacturer is required.	Submitted
3	1.5.2	The label applied is of Rosuvastatin calcium 5mg, whereas product approvals in RRA are for Rosuvastatin 5mg as calcium. Label needs to be revised along with requisite fee.	The firm has submitted corrected label but fee is not submitted.
4	3.2.P.8	Copies of executed BMRs of trial batches are required.	Submitted

Decision: Approved with following label;
Each film coated tablet contains;
Rosuvastatin as calcium……5mg
Letter shall be issued after submission of fee of Rs. 30,000/-
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 29.05.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.

As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2022-2023

1754.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 221-223, Sector 23 Korangi Industrial area, Karachi (DML No. 000350)**
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 221-223, Sector 23 Korangi Industrial area, Karachi (DML No. 000350)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 16146, Dt. 26.06.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 9878455734 PKR 45,000/- : Slip No. 182607788
	The proposed proprietary name / brand name	**FORTAZIM Plus IV Injection 2g + 0.5g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftazidime pentahydrate eq. to Ceftazidime….2g Avibactam sodium eq to Avibactum……0.5g
	Pharmacotherapeutic Group of (API)	Ceftazidime and beta-lactamase inhibitor ATC Code: J01DD52
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZAVICEFTA 2 G/0.5 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	**NA**

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			
2			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 22.01.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved.

1755.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)**

	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13945, Dt. 05.06.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 245200255
	The proposed proprietary name / brand name	**EMPAGEN-LM XR TABLETS 10MG/5MG/1000MG**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….10mg Linagliptin….5mg Metformin Hydrochloride….1000mg (as extended release)
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD27
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR TABLETS 5mg/2.5mg/1000mg 10mg/5mg/1000mg 12.5mg/2.5mg/1000mg 25mg/5mg/1000mg USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of GMP certificate issued by relevant health authorities for M/s Fuxin Long Rui Pharmaceutical Co. Ltd is required. (Submitted one is issued by Liaoning Fuxin Management committee for fluoride Industrial Development Zone)	Firm has submitted their response. The firm has submitted a written confirmation issued by Liaoning Medical Products Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1756.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: BLY-DNQ-N43N, Dt. 05.01.2024
	Details of fee submitted	PKR 75,000/- : Slip No. 45965531
	The proposed proprietary name / brand name	**EMPAGEN-LM XR TABLETS 25MG/5MG/1000MG**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….25mg Linagliptin….5mg Metformin Hydrochloride….1000mg (as extended release)
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD27
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR TABLETS 5mg/2.5mg/1000mg 10mg/5mg/1000mg 12.5mg/2.5mg/1000mg 25mg/5mg/1000mg USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of GMP certificate issued by relevant health authorities for M/s Fuxin Long Rui Pharmaceutical Co. Ltd is required. (Submitted one is issued by Liaoning Fuxin Management committee for fluoride Industrial Development Zone)	Firm has submitted their response. The firm has submitted a written confirmation issued by Liaoning Medical Products Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.

2	-	Copy of GMP certificate issued by relevant health authorities for M/s Anhui Haikang Pharmaceutical Co., Ltd - China is required. (Submitted one is issued by Anqing Biomedical Industry Association)	The firm has submitted a written confirmation issued by Anhui Mecical Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1757.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: DR8-3SY-GUQ5, Dt. 05.01.2024
	Details of fee submitted	PKR 75,000/- : Slip No. 9537919405
	The proposed proprietary name / brand name	**Empagen-LM XR Tablets 12.5mg/2.5mg/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….12.5mg Linagliptin….2.5mg Metformin Hydrochloride….1000mg (as extended release)
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD27
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR TABLETS 5mg/2.5mg/1000mg 10mg/5mg/1000mg 12.5mg/2.5mg/1000mg 25mg/5mg/1000mg USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply

1	-	Copy of GMP certificate issued by relevant health authorities for M/s Fuxin Long Rui Pharmaceutical Co. Ltd is required. (Submitted one is issued by Liaoning Fuxin Management committee for fluoride Industrial Development Zone)	Firm has submitted their response. The firm has submitted a written confirmation issued by Liaoning Medical Products Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.
2	-	Copy of GMP certificate issued by relevant health authorities for M/s Anhui Haikang Pharmaceutical Co., Ltd - China is required. (Submitted one is issued by Anqing Biomedical Industry Association)	The firm has submitted a written confirmation issued by Anhui Mecical Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1758.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. Amangarh, Nowshera, Khyber Pakhtunkhwa. (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: QU3-XLE-W7PP, Dt. 05.01.2024
	Details of fee submitted	PKR 75,000/- : Slip No. 54476671369
	The proposed proprietary name / brand name	**Empagen-LM XR Tablets 5mg/2.5mg/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….5mg Linagliptin….2.5mg Metformin Hydrochloride….1000mg (as extended release)
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD27
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR TABLETS 5mg/2.5mg/1000mg 10mg/5mg/1000mg 12.5mg/2.5mg/1000mg 25mg/5mg/1000mg USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of GMP certificate issued by relevant health authorities for M/s Fuxin Long Rui Pharmaceutical Co. Ltd is required. (Submitted one is issued by Liaoning Fuxin Management committee for fluoride Industrial Development Zone)	Firm has submitted their response. The firm has submitted a written confirmation issued by Liaoning Medical Products Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.
2	-	Copy of GMP certificate issued by relevant health authorities for M/s Anhui Haikang Pharmaceutical Co., Ltd - China is required. (Submitted one is issued by Anqing Biomedical Industry Association)	The firm has submitted a written confirmation issued by Anhui Mecical Administration wherein its written that material is exported to EU and manufacturer complies to GMP requirements.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 29.05.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2019-2020

1759.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Name, address of Manufacturing site.	**M/s Biolabs (pvt).ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad (DML No. 000286)**
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ **Is involved in none of the above (contract giver)**
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: JWE-XP8-35ZR
	Details of fee submitted	PKR 75000/- : Slip No. 28476038920
	The proposed proprietary name / brand name	**Onstron 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains Ondansetron (as hydrochloride dihydrate)….8mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondansetron 2 mg/ml solution for injection MHRA Approved.
	For generic drugs (me-too status)	Onset Injection

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			
2			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1760.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Name, address of Manufacturing site.	**M/s Biolabs (pvt).ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad (DML No. 000286)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: XRX-RA9-YMJT
	Details of fee submitted	PKR 75000/- : Slip No. 5109267901
	The proposed proprietary name / brand name	**Suno D3 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains Cholecalciferol (Vitamin D3)……5mg (eq. 200,000IU of Vitamin D)
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	**Innovator's Specifications.**
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Cholecalciferol Injection **(ANSM** France Approved)
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma (Reg #073183)
	Evaluation by PEC-IX	
	The applied product to be manufactured by M/s Biolabs (pvt). ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 323rd meeting are as follows: **Applicant Firm:** M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot No. 20, Phase 4, Hattar-Industrial Estate, KPK. **Manufacturer:** M/s Biolabs (pvt). ltd, Plot No. 145, Industrial Triangle, Kahuta road, Islamabad **Brand Name:** Sunray Injection 5mg/mL.	
Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1761.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Name, address of Manufacturing site.	**M/s Biolabs (pvt).ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad (DML No. 000286)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: D7Q-YAS-363P
	Details of fee submitted	PKR 75000/- : Slip No. 8144337268
	The proposed proprietary name / brand name	**Omper 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each lyophilized vial contains; Omeprazole sodium eq. to Omeprazole….40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	**Innovator's Specifications.**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Evaluation by PEC-IX	
	The applied product to be manufactured by M/s Biolabs (pvt). ltd, Plot No. 145, Industrial Triangle, Kahuta road, Islamabad has already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 324th meeting are as follows: **Applicant Firm:** M/s Nawan Laboratories (Pvt) Ltd, 136, Sector 15, Korangi Industrial Area,	

	Karachi **Manufacturer:** M/s Biolabs (pvt). ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad **Brand Name:** Oltrix Injection 40mg IV

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 22.01.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2022-2023

1762.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26541, Dt. 03.11.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 0888740003
	The proposed proprietary name / brand name	**LUMAGET 42mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Lumateperone tosylate eq. to Lumateperone….42mg
	Pharmacotherapeutic Group of (API)	Antipsychotics. Butyrophenone derivatives ATC Code: N05AD10
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CAPLYTA eq to 42mg base Capsule USFDA Approved.
	For generic drugs (me-too status)	**NA**

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			
2			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 24.03.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2022-2023

1763.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Haleon Pakistan Limited. Petaro Road, Jamshoro Pakistan(DML No. 000010)**
	Name, address of Manufacturing site.	M/s Haleon Pakistan Limited. Petaro Road, Jamshoro Pakistan(DML No. 000010)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25739, Dt. 24.10.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 3719881147
	The proposed proprietary name / brand name	**Panadol Dual Action Tablets 250mg + 125mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Paracetamol……250mg Ibuprofen……125mg
	Pharmacotherapeutic Group of (API)	Paracetamol combinations ATC Code: N02BE51
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	2x10's
	Proposed unit price	Rs. 200/-
	The status in reference regulatory authorities	ADVIL DUAL ACTION WITH ACETAMINOPHEN USFDA Approved.
	For generic drugs (me-too status)	**NA**

Evaluation by PEC-IX

S. No.	Section	Observation
1	-	Copy of AD attested invoice or clearance certificate issued by DRAP for drug substance (Ibuprofen) is required.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 24.03.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2021-2022

1764.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan (DML No. 000016)**
	Name, address of Manufacturing site.	M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: T51-31R-M9GQ Dt. 12.03.2024
	Details of fee submitted	PKR 30,000/- : Slip No. 4373223402
	The proposed proprietary name / brand name	**SYNPEP 375mg + 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen ……..... 375mg (Enteric coated core) Esomeprazole as magnesium trihydrate …... 20mg (Immediate released coat)
	Pharmacotherapeutic Group of (API)	Propionic acid derivatives ATC Code: M01AE52
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mylan-Naproxen / Esomeprazole MR 375/20mg tablet DIN: 02458608 Health Canada Approved
	For generic drugs (me-too status)	Glomov 375mg/20mg Tablet by M/s Global Pharmaceuticals (Reg#109339)

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1765.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan (DML No. 000016)**
	Name, address of Manufacturing site.	M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: PNN-1U4-S8ED Dt. 12.03.2024
	Details of fee submitted	PKR 30,000/- : Slip No. 60807795096
	The proposed proprietary name / brand name	**SYNPEP 500mg + 20mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen ……..... 500mg (Enteric coated core) Esomeprazole as magnesium trihydrate ….. 20mg (Immediate released coat)
	Pharmacotherapeutic Group of (API)	Propionic acid derivatives ATC Code: M01AE52
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mylan-Naproxen / Esomeprazole MR 500/20mg tablet DIN: 02443449 Health Canada Approved
	For generic drugs (me-too status)	Glomov 500mg/20mg Tablet by M/s Global Pharmaceuticals

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			
2			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1766.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)**
	Name, address of Manufacturing site.	M/s Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate Karachi. DML No. 000016
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 114/2022-DRAP (K) dated 05.08.2022 valid till 18.07.2024, issued by DRAP Karachi is submitted.
	Evidence of approval of manufacturing facility	Copy of Section approval letter No. 2-6/2018-Lic 9Vol-IV) dated 29.10.2020 is submitted. Capsule (General) Amendment.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 9615 dated 11.01.2023
	Details of fee submitted	**PKR 30,000/-** Slip No. 93988135494 dated 04.01.2023
	The proposed proprietary name / brand name	**URIEFA 4mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Silodosin……4mg
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists ATC Code: G04CA04
	Pharmaceutical form of applied drug	Hard gelatin oral capsule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rapaflo 4mg & 8mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Sildat 4mg Capsule Reg. No. 105264 M/s Sami Pharma Karachi.
	Name and address of API manufacturer.	M/s ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 130001-200705-2
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. Batch No. 13000-170802, 13000-170803, 13000-170804.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Silodosin 4mg Capsule Batch No. 21PD-191. **Reference product:** Urorec 4mg Capsule, Batch No. 19002, manufactured by M/s _____ **Tests done:** Description, identification, assay, dissolution, content uniformity, related substances. **CDP:** **F2 at pH 1.2:** More than 85% in 15 min **F2 at pH 4.5:** More than 85% in 15 min **F2 at pH 6.8:** More than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City China.		
API Lot No.	130001-200705-2		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-191	21PD-221	21PD-222
Batch Size	2500 Capsules	2500 Capsules	2500 Capsules
Manufacturing Date	09.2021	11.2021	11.2021
Date of Initiation	12.2021	12.2021	12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ200054 dated 22.07.2020 valid till 21.07.2023 issued by Zhejiang medical product administration china is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Silodosin JP** Batch No.: 13001-200705-2 Mfg date: - Retest: - Quantity: 200grams Invoice No.: TY12020918276 Invoice date: 18.09.2020 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Stability Cases

1767.	**Name and address ofmanufacturer / Applicant**	**M/s The Searle Company Limited, F-319, S.I.T.E. Karachi. (DML No. 000016)**
	Diary No. Date of R& I & fee	Dy.No. 19808, Dated:01.11.2017 R&I verified Rs.50,000/- vide slip no. 0714620 endorsed on 30.10.2017 Duplicate submitted vide Dy. No. 811 dated 15.01.2024
	Brand Name +Dosage Form +Strength	**TAPENDOL XR 250mg Tablets**
	Composition	Each film coated extended release tablet contains; Tapentadol HCl…….250mg
	Pharmacological Group	Other opioids N02AX06
	Type of Form	Form-5D
	Finished product Specifications	As per Innovator's Specifications.
	Pack size & Demanded Price	10's 14's 28's As per SRO
	Approval status of product in Reference Regulator Authorities	NUCYNTA ER EQ 250mg base USFDA Approved.
	Me-too status	Not available
	GMP status	Copy of GMP certificate valid till 18.07.2024 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s SYMED Labs Limited Unit-VI, Sy. 744, 745, 750, 751, 752 * 753 Mandollagudem Village Choutuppal (V), Choutuppal (M), Yadadri Bhuvanagiri Telangana India.
API Lot No.	6TDL 0040219
Description of Pack (Container closure system)	Sky blue colour, biconvex, oblong shaped film coated tablets, plain from both sides.
Stability StorageCondition	Real time: 30˚C ± 2˚C / 65% ± 5% RHAccelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 monthsAccelerated: 6 months

Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)	
Batch No.	**20PD-105**	**20PD-106**	**20PD-107**
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	05.2020	05.2020	05.2020
Date of Initiation	04.06.2020	04.06.2020	04.06.2020
No. of Batches	03		
Date of Submission	25.04.2022 (Dy. # 104472)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval ofapplications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and FinishedProduct Manufacturer	Submitted
iv.	Stability study data of API from APImanufacturer	Submitted
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concernedregulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of APIwith approval from DRAP (in case of	Submitted
	import).	
vii.	Protocols followed for conduction ofstability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies(where applicable)	Not required
x.	Complete batch manufacturing record ofthree stability batches.	Submitted
xi.	Record of comparative dissolution data(where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents likechromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software21CFR & audit trail reports on product testing.	Submitted

xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

S#	Observations	Reply of the firm
i	Specifications applied are Searle specs, Clarify.	The firm vide letter No DRA/PRV/REG/2024/80005-DH dated 16.02.2024 has responded to these queries. The firm has submitted that specifications of the product are as per innovator's. Fee of Rs. 7500/- vide slip No. 45471078428 is submitted for revision of specifications.
ii.	The label is of Tapentadol HCl 250mg, innovator product has a label of Tapentadol HCl eq to base 250mg. Clarify.	The firm has submitted that their applied label is Tapentadol (as hydrochloride)…250mg. It's a typographic error in application.
iii.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 18.07.2024 is submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1768.	**Name and address ofmanufacturer / Applicant**	**M/s Genix Pharma (Pvt.) Ltd. 44, 45-B Korangi Creek Road, Karachi. (DML No. 000351)**
	Diary No. Date of R& I & fee	Dy.No. 614, Dated:20.01.2015 R&I verified Rs. 50,000/- vide slip no. 0314116 endorsed on 09.10.2015 Duplicate submitted vide Dy. No. 804 dated 15.01.2024
	Brand Name +Dosage Form +Strength	**TAFLU Eye Drops**
	Composition	Each ml contains; Tafluprost…….0.015mg
	Pharmacological Group	Prostaglandin analogues S01EE05
	Type of Form	Form-5D
	Finished product Specifications	**Innovator Specifications**
	Pack size & Demanded Price	1ml, 2.5ml, 5ml As per SRO
	Approval status of product in Reference Regulator Authorities	Saflutan 15 micrograms/ml eye drops, solution MHRA Approved.
	Me-too status	Not available
	GMP status	Copy of GMP certificate valid up to: 12-06-2025 is submitted
	Remarks of the Evaluator	
STABILITY STUDY DATA		

Manufacturer of API	M/s Chirogate International Inc. Youth Plant, No. 2, Shih 4th Road, Yangmei Dist, Taoyuan City, Taiwan. China.
API Lot No.	K-374-1208
Description of Pack (Container closure system)	Clear colourless sterile solution filled in LDPE (Sterilized) Bottle 10ml
Stability Storage Condition	Real time: 5˚C ± 3˚ C Accelerated: 25 °C ± 2 °C / 60% ± 5% RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	**21SB-137-01**	**21SB-138-02**	**21SB-139-03**
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	01.2021	01.2021	01.2021
Date of Initiation	15.02.2021	15.02.2021	15.02.2021
No. of Batches	03		
Date of Submission	17.01.2024 (Dy. # 1022), initially submitted on 05.09.2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	**Documents to Be Provided**	**Status**
i.	Reference of previous approval ofapplications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and FinishedProduct Manufacturer	Submitted
iv.	Stability study data of API from APImanufacturer	Submitted
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concernedregulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of APIwith approval from DRAP (in case of	Submitted
	import).	
vii.	Protocols followed for conduction ofstability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies(where applicable)	Not required
x.	Complete batch manufacturing record ofthree stability batches.	Submitted

xi.	Record of comparative dissolution data(where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents likechromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Deferred Cases;

1769.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore.
	Details of Drug Sale License of importer	**License No**: 0000007064 **Address**: Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore. Address of Godown: NA **Validity**: 16-06-2022 **Status**: License to sell Drugs as Distributor. **Technical Person:** Ms. Madeeha Ashfaq CNIC No. 35202-3477405-8
	Name and address of marketing authorization holder (abroad)	M/s Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, Spain.
	Name, address of manufacturer(s)	**M/s Gland Pharma Limited,** Survey No. 143-148, 150& 151, Near Grandimnaisamma Cross Roads, DP Pally, Gandimaisamma mandal, Medchal Malkajiri district Hyderabad, Telangana, India.
	Name of exporting country	Spain.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 2021/063) dated 25.03.2021 issued by **Malta Medicines Authority**. Name and dosage form on the CoPP certificate mentioned is "Caspovitae 50mg powder for concentrate for solution for infusion" and name of the product license holder is Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, **Spain**. The certificate also confirms that the applied

		formulation is actually on the market in the exporting country. The name of importing country on CoPP is mentioned as Pakistan. **GMP:** Applicant has submitted legalized copy of GMP certificate No. UK GMP 39716 Insp GMP 39716/3187772 0005 dated 19.06.2017 issued by MHRA UK in the name of M/s Gland Pharma Limited, Survey No. 143-148, 150& 151, Near Grandimnaisamma Cross Roads, DP Pally, Gandimaisamma mandal, Medchal Malkajiri district Hyderabad, Telangana, **India** having its manufacturing site at same address. The certificate confirms that manufacturer complies with principles and guidelines of GMP laid down in Directive 2003/94/EC. As per Eudra GMP record, last inspection of the manufacturer was conducted on 16.09.2019 by MHRA UK.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of sole agency agreement. The agreement specifies that product license holder i.e. M/s Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, Spain appoints M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore to import below mentioned product. The document also emphasized that M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore is authorized distributor of the below mentioned products in Pakistan; *Anastrozole 1 mg x 26 film coated tablets* ***Caspofungin 50 x 1 vial*** *Abiraterone 250mg x 120 tablets*
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10481 dated 25-04-2022.
	Details of fee submitted	PKR 100,000/- vide slip No. 2057039 Dated: 28-05-2021 PKR 50,000/- vide slip No. 382118182681 Dated: 17.09.2021
	The proposed proprietary name / brand name	**Caspovitae 50mg powder for concentrate solution for infusion.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial contains:** Caspofungin Acetate 55.5mg equivalent to Caspofungin…….. 50mg.
	Pharmaceutical form of applied drug	White to off-white lyophilized powder or cake, filled in type I glass vial with butyl stopper and an aluminium seal with red plastic flip-off cap.
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use. ATC Code: J02AX04
	Reference to Finished product specifications	Ph. Eur. Specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	caspofungin 50 mg and 70 mg powder for concentrate for solution for infusion PL 1311/0605-0606 MHRA Approved.
	For generic drugs (me-too status)	Caspogin 50mg Reg. No. 106828 M/s AJM Pharma Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s DSM Sinochem Pharmaceuticals India (Pvt.) Ltd. Bhai Mohan Singh Nagar, Village Toansa, Distt. Ropar, Punjab, India. M/s Arch Pharmalabs Ltd. H Wing 4th Floor, Tex Centre Off Saki Vihar Road, Chandivali Andheri Mumbai.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (3141400239, 3141400256, 3141400258) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40 °C 75% RH: 16 days (degradation: 5% per day) 25 °C 65% RH: 2months (degradation: 16% per month) 5 °C : : 6 months(degradation: 3% per month) -18 °C : : 6 months (degradation: 1.6% per month)

		-70 ºC : : stability done upto 36 months The stability study is conducted at -70 ºC ± 5ºC. Batch No. 3141400239, 3141400256, 3141400258
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis [(ACR501, ACR502, ACR5030)Teva API], [(ATC601)DSP API], justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Cancidas Lot No. 2100510 manufactured by Merck UK exp date: 03.2015, by performing following tests; Appearance, water content, pH, dissolution rate, Completeness and clarity of solution, assay, , impurity A, impurity B and unknown impurities.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	White to off-white lyophilized powder or cake, filled in type I glass vial with butyl stopper and an aluminium seal with red plastic flip-off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 4 batches of drug product. **The real time stability study data is conducted at 2ºC - 8º C for 48 months**. Accelerated at 25±2°C/60±5%RH for 6 months. Batch No. [(ACR501, ACR502, ACR503) Teva API], [(ATC601) DSP API]. In use stability study of 24 hours is also submitted. Conducted at 18-25°C. Test points are at 12h and 24h.
	Therapeutic indications in USFDA.	CANCIDAS is a sterile, lyophilized product for intravenous (IV) infusion that contains a semisynthetic lipopeptide (echinocandin) compound synthesized from a fermentation product of *Glarea lozoyensis*. CANCIDAS is the first of a new class of antifungal drugs (glucan synthesis inhibitors) that inhibit the synthesis of β (1,3)-d-Glucan, an integral component of the fungal cell wall. **Indications and Usage** CANCIDAS is indicated for the treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (i.e. amphotericin B, lipid formulations of amphotericin B and/or itraconazole) CANCIDAS has not been studied as initial therapy for invasive aspergillosis.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm

1.	**-**	Notarized copy of letter of authorization/sole agency agreement is required.	Copy is submitted vide letter no. 26082023/01-RH dated 26.08.2023. Original is also seen. Firm will submit original at time of issuance of Registration letter.
2.	**-**	The country of origin of drug product appears to be India. The market authorization holder is of Spain and COPP submitted is of Malta. Clarification is required why COPP from country of origin is not submitted and why marketing authorization of Spain is not submitted when marketing authorization holder is in Spain.	The firm has submitted a declaration letter from M/s Galenicum Ecosystem (MA holder) stating the following; *"We would like to clarify that Galenicum's main business in Europe is to develop generic products and license them to third-party companies.* *Due to this, Galenicum usually does not commercialize under its own brand name or does not own the products in Europe. Even though we are the owners of the intellectual property, our products are commercialized in Europe under customer's brand name and ownership.* *Galenicum's product has been submitted in several EU countries by Decentralise Procedure (DCP), therefore the dossier submitted in all these countries is the same in terms of qualitative composition and quantitative proportional composition and are manufactured by the same process.* *Even though Galenicum does not normally register under its name nor commercialize under its ownership, in the case of Caspofungin we have an exception and one of the licenses in Malta and Spain are under Galenicum's name, having the product marketed only in Malta."*
3.	**-**	GMP certificate of drug substance manufacturer is required.	Submitted vide letter no. 26082023/01-RH dated 26.08.2023. M/s TEVA API India Pvt Ltd. M/s TEVA Pharmaceuticals Ltd. Hungary.
4.	**3.2.S**	Some testing documents attached are of M/s M/s Arch Pharmalabs Ltd. H Wing 4th Floor, Tex Centre Off Saki Vihar Road, Chandivali Andheri Mumbai. Clarification is required regarding that is drug product manufacturer sourcing API from multiple sources or otherwise. What is role of M/s Arch Pharmalabs in processing of drug substance.	The firm has submitted a declaration letter from M/s Galenicum Ecosystem (MA holder) stating the following; *"Please note that the question mentions an API source that was discontinued due to commercial reasons. The API source that must be considered for Caspofungin 50mg and 70mg powder for concentrate for solution for*

			infusion, is TEVA Pharmaceutical Industrial Ltd. (TAPI)"
5.	3.2.P.5.4	In batch analysis of 3 batches it is stated that API used was manufactured by Teva and for one batch it was manufactured by DSM. The S part is required from all API manufacturers (prequalified suppliers) who's API will be used to manufacture the drug product.	The vide letter no. 26082023/01-RH dated 26.08.2023 has submitted S part of module 3 for drug substance from M/s TEVA Pharmaceutical Industries. Two manufacturing sites are mentioned; TEVA API India and TEVA Hungary. Stability studies data of Indian site is submitted only.

Decision of 331st Meeting of the Board: The Board deferred the case for further clarification regarding free sale status of the applied product in country of origin and registration status in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Remarks of Evaluator:

The firm vide letter No. 04032024/01-RH dated 04.03.2024 has requested for change of address to Ground Floor 6-Judicial Colony, Phase 1 (Ext) Shahrah Nazaria e Pakistan Lahore. Firm has submitted copy of new DSL along with fee of Rs 7500/- vide slip No. 93004893767 and revised Form-5F

The firm vide letter No. 07032024/01-RH dated 07.03.2024 has submitted a legalized COPP having following details;

Issuing Agency: Spanish Agency for Medicines and Medical Devices (AEMPS)
Number of Certificate: 2023/03577
Date of issue: 27.09.2017 (very old)
CSV for verification at link of AEMPS https://localizador.aemps.es : TGPCQ2Q2E3

In submitted certificate, the last page is legalized, rest of the pages are pinned separately so they were not sealed with last page at time of legalization.
Further at page 2 of 6, at serial No. 1.4 in front of statement "***Is this product actually on the market in the exporting country***" word "***YES***" is mentioned.
When the same certificate is verified from online database of AEMPS Spain, word ***"NO"*** is mentioned in front of this statement which indicates tempering of original document to change the word "**NO"** to "**Yes".**

Decision: The Registration Board took serious notice of the matter of submission of document having different text than the one available on official website of AEMPS Spain and deferred the case for submission of clarification by the firm regarding the difference of text as mentioned.

1770.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore.
	Details of Drug Sale License of importer	**License No**: 0000007064 **Address**: Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore. Address of Godown: NA **Validity**: 16-06-2022 **Status**: License to sell Drugs as Distributor. **Technical Person:** Ms. Madeeha Ashfaq CNIC No. 35202-3477405-8
	Name and address of marketing authorization holder (abroad)	M/s Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, Spain.
	Name, address of manufacturer(s)	**M/s Gland Pharma Limited,** Survey No. 143-148, 150& 151, Near Grandimnaisamma Cross Roads, DP Pally, Gandimaisamma mandal, Medchal

		Malkajiri district Hyderabad, Telangana, India.
	Name of exporting country	Spain.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 2021/064) dated 25.03.2021 issued by **Malta Medicines Authority**. Name and dosage form on the CoPP certificate mentioned is "Caspovitae 70mg powder for concentrate for solution for infusion" and name of the product license holder is Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, **Spain**. The certificate also confirms that the applied formulation is actually on the market in the exporting country. The name of importing country on CoPP is mentioned as Pakistan. **GMP:** Applicant has submitted legalized copy of GMP certificate No. UK GMP 39716 Insp GMP 39716/3187772 0005 dated 19.06.2017 issued by MHRA UK in the name of M/s Gland Pharma Limited, Survey No. 143-148, 150& 151, Near Grandimnaisamma Cross Roads, DP Pally, Gandimaisamma mandal, Medchal Malkajiri district Hyderabad, Telangana, **India** having its manufacturing site at same address. The certificate confirms that manufacturer complies with principles and guidelines of GMP laid down in Directive 2003/94/EC. As per Eudra GMP record, last inspection of the manufacturer was conducted on 16.09.2019 by MHRA UK.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of sole agency agreement. The agreement specifies that product license holder i.e. M/s Galenicum Health S.L, Diagonal 123, Planta 11 08005, Barcelona, Spain appoints M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore to import below mentioned product. The document also emphasized that M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793 D, Block C, Faisal Town, Lahore is authorized distributor of the below mentioned products in Pakistan; ***Caspofungin 70 x 1 vial***
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10482 dated 25-04-2022.
	Details of fee submitted	PKR 100,000/- vide slip No. 2057040 Dated: 28-05-2021 PKR 50,000/- vide slip No. 2662898479 Dated: 17.09.2021
	The proposed proprietary name / brand name	**Caspovitae 70mg powder for concentrate solution for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial contains:** Caspofungin Acetate 77.7mg equivalent to Caspofungin…….. 70mg.
	Pharmaceutical form of applied drug	White to off-white lyophilized powder or cake, filled in type I glass vial with butyl stopper and an aluminium seal with red plastic flip-off cap.
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use. ATC Code: J02AX04
	Reference to Finished product specifications	Ph. Eur. Specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	caspofungin 50 mg and 70 mg powder for concentrate for solution for infusion PL 1311/0605-0606 MHRA Approved.
	For generic drugs (me-too status)	Caspogin 70mg Reg. No. 106829 M/s AJM Pharma Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s DSM Sinochem Pharmaceuticals India (Pvt.) Ltd. Bhai Mohan Singh Nagar, Village Toansa, Distt. Ropar, Punjab, India. M/s Arch Pharmalabs Ltd. H Wing 4th Floor, Tex Centre Off Saki Vihar Road, Chandivali Andheri Mumbai.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (3141400239, 3141400256, 3141400258) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40 ºC 75% RH: 16 days (degradation: 5% per day) 25 ºC 65% RH: 2months (degradation: 16% per month) 5 ºC : : 6 months(degradation: 3% per month) -18 ºC : : 6 months (degradation: 1.6% per month) -70 ºC : : stability done upto 36 months The stability study is conducted at -70 ºC ± 5ºC. Batch No. 3141400239, 3141400256, 3141400258
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis [(ACS501, ACS502)Teva API], [(ACU601)DSP API], justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Cancidas Lot No. 2081510 manufactured by Merck UK exp date: 10/2014, by performing following tests; Appearance, water content, pH, dissolution rate, Completeness and clarity of solution, assay, , impurity A, impurity B and unknown impurities.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	White to off-white lyophilized powder or cake, filled in type I glass vial with butyl stopper and an aluminium seal with red plastic flip-off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 4 batches of drug product. **The real time stability study data is conducted at 2ºC - 8º C for 48 months**. Accelerated at 25±2°C/60±5%RH for 6 months. Batch No. [(ACS501, ACS502)Teva API], [(ACU601)DSP API]. In use stability study of 24 hours is also submitted. Conducted at 18-25°C. Test points are at 12h and 24h.
	Therapeutic indications in USFDA.	CANCIDAS is a sterile, lyophilized product for intravenous (IV) infusion that contains a semisynthetic lipopeptide (echinocandin) compound synthesized from a fermentation product of *Glarea lozoyensis*. CANCIDAS is the first of a new class of antifungal drugs (glucan synthesis inhibitors) that inhibit the synthesis of β (1,3)-d-Glucan, an integral component of the fungal cell wall. **Indications and Usage** CANCIDAS is indicated for the treatment of invasive aspergillosis in patients who are refractory to or

		intolerant of other therapies (i.e. amphotericin B, lipid formulations of amphotericin B and/or itraconazole) CANCIDAS has not been studied as initial therapy for invasive aspergillosis.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Notarized copy of letter of authorization/sole agency agreement is required.	Copy is submitted vide letter no. 26082023/01-RH dated 26.08.2023. Original is also seen. Firm will submit original at time of issuance of Registration letter.
2.	-	The country of origin of drug product appears to be India. The market authorization holder is of Spain and COPP submitted is of Malta. Clarification is required why COPP from country of origin is not submitted and why marketing authorization of Spain is not submitted when marketing authorization holder is in Spain.	The firm has submitted a declaration letter from M/s Galenicum Ecosystem (MA holder) stating the following; *"We would like to clarify that Galenicum's main business in Europe is to develop generic products and license them to third-party companies.* *Due to this, Galenicum usually does not commercialize under its own brand name or does not own the products in Europe. Even though we are the owners of the intellectual property, our products are commercialized in Europe under customer's brand name and ownership.* *Galenicum's product has been submitted in several EU countries by Decentralise Procedure (DCP), therefore the dossier submitted in all these countries is the same in terms of qualitative composition and quantitative proportional composition and are manufactured by the same process.* *Even though Galenicum does not normally register under its name nor commercialize under its ownership, in the case of Caspofungin we have an exception and one of the licenses in Malta and Spain are under Galenicum's name, having the product marketed only in Malta."*
3.	-	GMP certificate of drug substance manufacturer is required.	Submitted vide letter no. 26082023/01-RH dated 26.08.2023. M/s TEVA API India Pvt Ltd. M/s TEVA Pharmaceuticals Ltd. Hungary.
4.	**3.2.S**	Some testing documents attached are of M/s M/s Arch Pharmalabs Ltd. H Wing 4th Floor, Tex Centre Off Saki	The firm has submitted a declaration letter from M/s Galenicum Ecosystem (MA holder) stating the following;

		Vihar Road, Chandivali Andheri Mumbai. Clarification is required regarding that is drug product manufacturer sourcing API from multiple sources or otherwise. What is role of M/s Arch Pharmalabs in processing of drug substance.	*"Please note that the question mentions an API source that was discontinued due to commercial reasons. The API source that must be considered for Caspofungin 50mg and 70mg powder for concentrate for solution for infusion, is TEVA Pharmaceutical Industrial Ltd. (TAPI)"*
5.	3.2.P.5.4	In batch analysis of 2 batches it is stated that API used was manufactured by Teva and for one batch it was manufactured by DSM. The S part is required from all API manufacturers (prequalified suppliers) who's API will be used to manufacture the drug product.	The vide letter no. 26082023/01-RH dated 26.08.2023 has submitted S part of module 3 for drug substance from M/s TEVA Pharmaceutical Industries. Two manufacturing sites are mentioned; TEVA API India and TEVA Hungary. Stability studies data of Indian site is submitted only.

Decision of 331st Meeting of the Board: The Board deferred the case for further clarification regarding free sale status of the applied product in country of origin and registration status in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Remarks of Evaluator:
The firm vide letter No. 04032024/02-RH dated 04.03.2024 has requested for change of address to **Ground Floor 6-Judicial Colony, Phase 1 (Ext) Shahrah Nazaria e Pakistan Lahore**. Firm has submitted copy of new DSL along with fee of Rs 7500/- vide slip No. 811303363 and revised Form-5F

The firm vide letter No. 07032024/02-RH dated 07.03.2024 has submitted a legalized COPP having following details;
Issuing Agency: Spanish Agency for Medicines and Medical Devices (AEMPS)
Number of Certificate: 2023/03578
Date of issue: 27.09.2017 (very old)
CSV for verification at link of AEMPS https://localizador.aemps.es : YRFXQA47B1

In submitted certificate, the last page is legalized, rest of the pages are pinned separately so they were not sealed with last page at time of legalization.
Further at page 2 of 6, at serial No. 1.4 in front of statement "***Is this product actually on the market in the exporting country***" word "***YES***" is mentioned.
When the same certificate is verified from online database of AEMPS Spain, word ***"NO"*** is mentioned in front of this statement which indicates tempering of original document to change the word "**NO"** to "**Yes".**

Decision: The Registration Board took serious notice of the matter of submission of document having differen than the one available on official website of AEMPS Spain and deferred the case for submission of clarificatio the firm regarding the difference of text as mentioned.

1771.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi. DML No. 000488
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 29.09.2021 based on inspection conducted on 27.09.2021. Valid till 26.09.2023.
	Evidence of approval of manufacturing facility	Firm has submitted copies of inspection reports indicating Liquid injection section. Liquid injection section is also mentioned in GMP certificate provided. **Section approval letter is not submitted.**
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7347 dated 15.03.2022
	Details of fee submitted	PKR 75,000/- Slip No. 4716766287 dated 20.01.2022
	The proposed proprietary name / brand name	**L-CAINE 1:100,000 Dental Cartridge**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1.8ml glass cartridge contains; Lignocaine HCl (BP)…..36mg Adrenaline (equivalent to base) USP…0.018mg
	Pharmacotherapeutic Group of (API)	ANESTHETICS, LOCAL, lidocaine, combinations. ATC Code: N01BB52
	Pharmaceutical form of applied drug	Not submitted
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	50's x 1.8ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	2% Xylocaine DENTAL with epinephrine 1:100,000 (Lidocaine HCl 2% and Epinephrine 1:100,000 Injection) USFDA. Discontinued: Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**<u>Lignocaine HCl</u>** M/s Gufic Biosciences Limited, National Highway No. 8, Noor Grid, Al Post Kabilpore, Distt nasvan (Gujrat) India. **<u>Adrenaline (Epinephrine);</u>** M/s IFFECT Chemphar Co. Ltd. 2603, International Science and Technology Building, 3007 Shennan Road, Futian District Shenzhen, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Lidocaine HCl: LHCP1120817 Adrenaline: IF-AD-1811220
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 (36 months for Adrenaline) months. **Lidocaine HCl Batches:** 1159, 1160, 1161. **Adrenaline Batches:** IF-AD-160316, IF-AD160317, IF-AD-160318
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Lignocaine HCl** M/s Gufic Biosciences Limited, National Highway No. 8, Noor Grid, Al Post Kabilpore, Distt nasvan (Gujrat) India. **Adrenaline (Epinephrine);** M/s IFFECT Chemphar Co. Ltd. 2603, International Science and Technology Building, 3007 Shennan Road, Futian District Shenzhen, China.
API Lot No.	Not submitted
Description of Pack (Container closure system)	Not submitted
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-101	T-102	T-103
Batch Size			
Manufacturing Date	10.2017	10.2017	10.2017
Date of Initiation	07.2017	07.2017	07.2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Adrenaline** Batch No. : IF-AD-181120 Quantity: 500gm Mfg: 11.2020 Exp. 19.11.2021 Invoice No. SIFI 190201-1 Invoice Date: 12.03.2019 Cleared by AD I&E DRAP Karachi on 28.13.2019 **Lignocaine HCl BP** Batch No.: Not mentioned Quantity: 25kg Mfg: Not mentioned Exp. Not mentioned Invoice No. NBEXBD2223000249 Invoice Date: 03.03.2020 Cleared by AD I&E DRAP Karachi on 20.05.2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted. The hand written COA date of October 2017. Manufacturing date is also mentioned as October 2017, but chromatograms are dated as July 2017 and stability testing is also initiated from July 2017.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of section approval (Cartridge or PFS or vial section) is required.	Firm has submitted reply vide letter No. nil dated 24.08.2023 copy of section approval letter No. 2-4/98-Lic(Pt-I) dated 07.06.2022. The firm has Liquid Injection Vial/Amoule (General) section.

			The firm does not have the required section for the applied product (Dental Cartridge)
2.	-	The RRA reference submitted is discontinued. Valid evidence of RRA approval is required.	The applied product is 1.8ml dental cartridge with label of Lignocaine HCl (BP) 36mg & Adrenaline (equivalent to base) 0.018mg. Firm has submitted reference of health Canada approved product having strength of Epinephrine 0.01mg/ml and Lidocaine HCl 20mg/ml Valid RRA reference is not submitted.
3.	-	• AD Attested invoices and clearance documents of both drug substances are required. • GMP certificate and manufacturing authorization of both API manufacturers is required.	Copies of invoices are submitted. Invoices are dated 2019 and 2020 while trial batches were manufactured in 2017. Copies of GMP certificates are submitted.
4.	3.2.P.2	• With Adrenaline words 'equivalent to base' are mentioned, is it being used as a salt in the formulation? The COA and details submitted for drug substance indicate that material used is not a salt and is in base form. Clarification is required why equivalent to base is mentioned when salt is not used. • Also a comparison of applied formulation with innovator is required along with justification of any deviation. (The innovator uses tartrate salt of adrenaline in their formulation) • In comparative analysis of Ph, p-kort Injection is mentioned as reference product where in tabulated data Medicaine Injection is mentioned. • Detailed procedure of drug release profiling test is required. How it was done, in what media it was done and justification is required that why drug is being released in to something upto 50 minutes in a liquid injection formulation. **(the firm has submitted comparison of drug release profile of their product with Medicaine injection over a time period of 50 minutes. Such comparison in liquid injections is not possible and indicate)** • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required.	The firm has not submitted clarification of any point. The firm has resubmitted similar data with multiple discrepancies that was initially submitted. Further firm has submitted a copy of invoice of DVAGO Pakistan regarding purchase of Xylocaine injection as reference product from local market. This product cannot be a reference product for a dental cartridge. In all documents submitted, adrenaline base is mentioned, innovator uses tartrate salt of adrenaline.

		• In drug release certificate, Primla Topical cream is mentioned. What is its use in drug release of L-Caine Injection.	
5.	3.2.P.3.5	Refer to SOP No. OPL/PD/SOP-050 titled Operation of cartridge filling machine: Point 17: "*Unload one box of sterilized cartridge in feeding hopper and check the alignment of the needles and neck of the cartridges*" Detailed description of product is required that whether it is a cartridge vial to be used in a dental syringe or is it a pre-filled syringe ready to use?	The firm has not submitted clarification of any point. The firm has resubmitted similar data with multiple discrepancies that was initially submitted.
6.	3.2.P.3.5	In manufacturing details and BMRs it is not mentioned how cartridges will be sterilized, detailed description of manufacturing process is required covering every step. (how are cartridges sterilized, if needle are also used, how are they sterilized and handled?)	The firm has not submitted clarification.
7.	3.2.P.5	In analytical method validation, general procedures and few summary tables are submitted only. Performance data of method validation studies is required for every test being done on drug product.	The firm has submitted copies of calculation sheet and chromatograms. The chromatograms are clearly pasted over page having header of firm as images of chromatograms are stretched to fit the page.
8.	3.2.P.7	In packing material inspection report, why registration No. 029118 is written when its of opth-Cyclovir Ophthalmic Ointment.	No clarification is submitted, again same copy of packing material inspection report having registration No. 029118 is submitted.
9.	3.2.P.8	• Number of units in each trial batch is required along with justification that they are sufficient for all tests conducted during stability studies. • Clear description of drug product is required, including pharmaceutical form, appearance etc. • The manufacturing date and testing as per hand written COA indicate batches were manufactured in October 2017 whereas chromatograms are dated as of July 2017 and stability studies are also mentioned from July 2017. • Further the product record submitted on BMR like sheets indicate manufacturing of batches in June 2020.	The firm has not submitted any clarification. Same old data sheets are submitted in reply.
10.		**General Remarks:** The issues in submitted data, then not providing clarification of any query and resubmitting data full of discrepancies does not support scientifically the manufacturing, testing and performance of stability studies of trial batches.	

Decision of 331st RB: The board discussed and deliberated on the case and decided to defer the case and give a final chance for submission of clear and candid reply against the deficiencies

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of section approval (Cartridge or PFS or vial section) is required.	The firm has submitted revised reply vide letter No. nil dated 07.12.2023. As per submitted reply, **the firm does not have required section for applied product.**
2.	-	The RRA reference submitted is discontinued. Valid evidence of RRA approval is required.	The firm has submitted reference of 2% NUROCAIN DENTAL WITH ADRENALINE 1:100,000 2.2mL injection cartridge, approved in TGA Australia. The formulation is; adrenaline (epinephrine) acid tartrate 18.2 microgram/mL Equivalent: adrenaline (epinephrine) 10 microgram/mL lidocaine hydrochloride monohydrate 21.3 mg/mL Equivalent: lidocaine hydrochloride 20 mg/mL Salt of adrenaline is different than the applied product. As per BMR the firm is using Adrenaline base.
3.	-	• AD Attested invoices and clearance documents of both drug substances are required. • GMP certificate and manufacturing authorization of both API manufacturers is required.	The firm has stated that incorrect invoice was attached by mistake. Their trial batches were manufactured by using Lignocaine HCl imported for their registered product ANSCON Jelly.
4.	3.2.P.2	• With Adrenaline words 'equivalent to base' are mentioned, is it being used as a salt in the formulation? The COA and details submitted for drug substance indicate that material used is not a salt and is in base form. Clarification is required why equivalent to base is mentioned when salt is not used. • Also a comparison of applied formulation with innovator is required along with justification of any deviation. (The innovator uses tartrate salt of adrenaline in their formulation) • In comparative analysis of Ph, p-kort Injection is mentioned as reference product where in tabulated data Medicaine Injection is mentioned. • Detailed procedure of drug release profiling test is required. How it was done, in what media it was done and justification is required	The firm has stated that all these issues are typographic errors.

		that why drug is being released in to something upto 50 minutes in a liquid injection formulation. **(the firm has submitted comparison of drug release profile of their product with Medicaine injection over a time period of 50 minutes. Such comparison in liquid injections is not possible and indicate)** • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required. • In drug release certificate, Primla Topical cream is mentioned. What is its use in drug release of L-Caine Injection.	The firm has submitted a copy of invoice dated 16.09.2016 for purchase of 2% Nurocain dental 1 unit only.
5.	3.2.P.3.5	Refer to SOP No. OPL/PD/SOP-050 titled Operation of cartridge filling machine: Point 17: "*Unload one box of sterilized cartridge in feeding hopper and check the alignment of the needles and neck of the cartridges*" Detailed description of product is required that whether it is a cartridge vial to be used in a dental syringe or is it a pre-filled syringe ready to use?	The firm has stated that it was a typographic mistake and copy of revised SOP is submitted.
6.	3.2.P.3.5	In manufacturing details and BMRs it is not mentioned how cartridges will be sterilized, detailed description of manufacturing process is required covering every step. (how are cartridges sterilized, if needle are also used, how are they sterilized and handled?)	The firm has stated that supplied cartridges are sterilized by autoclaving before manufacturing process.
7.	3.2.P.5	In analytical method validation, general procedures and few summary tables are submitted only. Performance data of method validation studies is required for every test being done on drug product.	The firm has submitted performance data od method validation, but chromatograms appear edited.
8.	3.2.P.7	In packing material inspection report, why registration No. 029118 is written when its of opth-Cyclovir Ophthalmic Ointment.	The firm has stated that it was by mistake.
9.	3.2.P.8	• Number of units in each trial batch is required along with justification that they are sufficient for all tests conducted during stability studies. • Clear description of drug product is required, including pharmaceutical form, appearance etc. • The manufacturing date and testing as per hand written COA indicate batches were manufactured in	The firm has stated that batch size is of 1 litre and it produces 500 units. 20 units are required for testing at one time point, from 500 units, testing upto 36 months is possible. In clear description the firm has stated that its "clear colorless solution", again the firm has not informed that it's a vial or cartridge.

		October 2017 whereas chromatograms are dated as of July 2017 and stability studies are also mentioned from July 2017. • Further the product record submitted on BMR like sheets indicate manufacturing of batches in June 2020.	The firm has stated that batches were manufactured in july 2017, the date on COA are typographic error. Copies of detailed BMR are submitted. But again as per BMR, the firm is using adrenaline base in their formulation, and its not clear what will be the container closure system of the product.
10.	**General Remarks:** The reply of the firm is not satisfactory.		

Decision: The board deferred the case for

- **opinion of licensing division for manufacturing of dental cartridges in vial section and**
- **submission of justifiable response to above deficiencies by the firm.**

1772.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi. DML No. 000488
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 29.09.2021 based on inspection conducted on 27.09.2021. Valid till 26.09.2023.
	Evidence of approval of manufacturing facility	Firm has submitted copies of inspection reports indicating steroid injectable section. **Section approval letter is not submitted.**
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7349 dated 15.03.2022
	Details of fee submitted	PKR 30,000/- Slip No. 8055658374 dated 20.01.2022
	The proposed proprietary name / brand name	**M-Kort 40mg suspension for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains Methylprednisolone acetate…….40mg
	Pharmacotherapeutic Group of (API)	Glucocorticoids ATC Code: H02AB04
	Pharmaceutical form of applied drug	Not submitted.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEPO-MEDROL 40MG/ML SUSPENSION FOR INJECTION

		MHRA Approved.
	For generic drugs (me-too status)	Depo Medrol 40mg Injection Reg No. 000606 M/s Pfizer Pakistan Ltd.
	Name and address of API manufacturer.	M/s Framabios, VIA Pavia, 1-27027 Gropello Cairoli PV, Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No: 2178SM0 tested on 05.09.2021
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Batches:** 0011115, 0021115, 0031115.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Batches: T-101 (04.01.2020), T-102(06.01.2020), T-103 (08.01.2020)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Test Product: M-Kort Injection Reference Product: Depo-Medrol Injection No other details given.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Framabios, VIA Pavia, 1-27027 Gropello Cairoli PV, Italy.
API Lot No.	
Description of Pack	

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-101	T-102	T-103
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	01.2020	01.2020	01.2020
Date of Initiation	01.2020	01.2020	01.2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	A copy of registration letter is submitted where K-Cort 40mg/ml injection is registered vide Reg. No. 034395 having triamcinolone acetonide as its active.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of section approval (steroid injection vial) is required.	Firm has submitted copy of renewal letter wherein Injection Vial/Ampoule (Steroid) section is mentioned.
2.	-	• AD Attested invoices and clearance documents of both drug substances are required. • GMP certificate and manufacturing authorization of API manufacturer is required.	Clearance certificate or AD attested invoice is not submitted. Copy of GMP certificate is submitted.
3.	3.2.S.4.3	In testing method validation, under heading of detection of impurities of methyl prednisolone, the chromatogram time stamped as 9.01.2020 3:34:38 pm is exactly same as the one given in real time stability studies of batch T-101 acquired for Standard M.kort TB101, TB102, TB103.	No clarification is submitted. Firm has resubmitted documents which were initially submitted in dossier.

		Why your own chromatogram is copy pasted on a paper having letter head of drug substance manufacturer (M/s Farmabios Italy) Actual data of impurity profiling and drug substance analysis by the drug substance manufacturer is required.	
4.	3.2.P.2	• The drug substance is tested on 05.09.2021 and batches are manufactured in 2020. • What is use of finished drug product in comparative analysis of calibration curve? Why a calibration curve generated by using test product and reference product? How assay values of finished products are ranged from 0 to 203.72? • A figure of drug release profile comparison is submitted. Detailed procedure and media used for drug release profile comparison is required. • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required.	No clarification is submitted regarding any point only a copy of invoice of purchase of Depo Medrol Injection dated 07.09.2019 is submitted.
5.	3.2.P.2	As per drug release certificate, following tests are not performed; i. Uniformity of dosage units ii. Particle size iii. Sterility iv. BET v. Assay Why drug release is mentioned in drug release certificate with range of 75%-133%, and result of your product is 112%. The assay range as per USP is 90%-110%, your product is out of specs if its assay value.	No clarification is submitted. Firm has again submitted same Drug Release Certificate with Drug release value of 75%-133%. It is not clarified how drug release will be assessed. This test is also not mentioned in USP monograph of the product.
6.	3.2.P.3.5	Why batch numbers are same as that of product L-Caine? Why unique batch numbers are not allotted to each product?	No justification is provided. All documents are resubmitted by addition of suffix –MK by hand in batch numbers.
7.	3.2.P.5	The analytical methods (assay and other tests) are totally different from USP. The solvent system, method of preparation of sample, column etc are all different. The assay range is between 90-115%, pH range is between 3.0-7.5, In USP these ranges are 90-110% and 3.0-7.0. Why USP monograph is not followed.	No clarification is submitted. Revised specs and testing method as per USP us submitted. Performance data is not submitted.
8.	3.2.P.8	• Clear description of drug product is required, including pharmaceutical form, appearance etc.	Description of container closure system is submitted. No clarification is submitted for difference of pH values. New sheets with initial pH

		• The initial pH of Batch T-101 in real time studies is 5.8 and in accelerated is 4.1, why this value is different? Is there such large pH variation between vials of same batch? Similar issue is observed in stability summary sheets of batches T-102 and T-103. And pH values are exactly same for every batch, are they copy pasted on summary sheets? • The assay values on accelerated and real time stability sheets are totally same, it indicates that these are also copy pasted and not based on performed tests.	value of 5.6 are submitted. This value is again completely different from previously submitted data.
9.		**General Remarks:** The issues in submitted data, then not providing clarification of any query and resubmitting data full of discrepancies does not support scientifically the manufacturing, testing and performance of stability studies of trial batches.	

Decision of 331st meeting of RB: The board discussed and deliberated on the case and decided to defer the case to give a final chance for submission of clear and candid reply against the deficiencies.

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of section approval (steroid injection vial) is required.	The firm vide letter No. nil dated 30.11.2023 has submitted revised reply. Copy of section approval letter No. 2-4/98-Lic(Pt-I) dated 07.06.2022 I submitted wherein Injection vial/ampoule (steroid) section is mentioned.
2.	-	• AD Attested invoices and clearance documents of both drug substances are required. • GMP certificate and manufacturing authorization of API manufacturer is required.	Copy of GMP certificate is submitted. Copies of invoices are submitted but are not attested by AD I&E. It is submitted that material was received through DHL.
3.	3.2.S.4.3	In testing method validation, under heading of detection of impurities of methyl prednisolone, the chromatogram time stamped as 9.01.2020 3:34:38 pm is exactly same as the one given in real time stability studies of batch T-101 acquired for Standard M.kort TB101, TB102, TB103. Why your own chromatogram is copy pasted on a paper having letter head of drug substance manufacturer (M/s Farmabios Italy) Actual data of impurity profiling and drug substance analysis by the drug substance manufacturer is required.	The firm has stated that *"During making copy of documents printer take multiple pages and printed the content of pages on one page. That is why data of one page printed on other page"* Validation data of method of analysis done by drug substance manufacturer is submitted.
4.	3.2.P.2	• The drug substance is tested on 05.09.2021 and batches are manufactured in 2020. • What is use of finished drug product in comparative analysis of	The firm has stated that drug substance was purchased in September 2019. Similar material was again purchased in 2021 and by mistake its COA was enclosed.

		calibration curve? Why a calibration curve generated by using test product and reference product? How assay values of finished products are ranged from 0 to 203.72? • A figure of drug release profile comparison is submitted. Detailed procedure and media used for drug release profile comparison is required. • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required.	The firm has stated that new updated test reports for drug release are attached in dossier. Copy of invoice for purchase of ten units of Depo Medrol Injection, dated 07.09.2019 is submitted.
5.	3.2.P.2	As per drug release certificate, following tests are not performed; i. Uniformity of dosage units ii. Particle size iii. Sterility iv. BET v. Assay Why drug release is mentioned in drug release certificate with range of 75%-133%, and result of your product is 112%. The assay range as per USP is 90%-110%, your product is out of specs if its assay value.	Updated product analysis report is submitted.
6.	3.2.P.3.5	Why batch numbers are same as that of product L-Caine? Why unique batch numbers are not allotted to each product?	
7.	3.2.P.5	The analytical methods (assay and other tests) are totally different from USP. The solvent system, method of preparation of sample, column etc are all different. The assay range is between 90-115%, pH range is between 3.0-7.5, In USP these ranges are 90-110% and 3.0-7.0. Why USP monograph is not followed.	The firm has stated that they have updated analytical methods as per USP. Corrected documents with same old date (i.e. 10-2017) are again submitted. Indicating changing of document content without properly following principles of QMS.
8.	3.2.P.8	• Clear description of drug product is required, including pharmaceutical form, appearance etc. • The initial pH of Batch T-101 in real time studies is 5.8 and in accelerated is 4.1, why this value is different? Is there such large pH variation between vials of same batch? Similar issue is observed in stability summary sheets of batches T-102 and T-103. And pH values are exactly same for every batch, are they copy pasted on summary sheets? • The assay values on accelerated and real time stability sheets are totally	Container closure system is mentioned as 1ml glass vial. The firm has stated that the typist did this by mistake, the typist did not compile the real data of the analysis.

		same, it indicates that these are also copy pasted and not based on performed tests.	
9.		**General Remarks:** The chromatograms submitted with the reply appear edit. The reply of the firm is not satisfactory.	

Decision: The board deferred the case for submission of candid and justifiable response by the firm for mentioned observations.

1773.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s. Ophth Pharma (Pvt.) Ltd. Plot No. 241, Sector 24, Korangi Industrial Area, Karachi. DML No. 000488
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 29.09.2021 based on inspection conducted on 27.09.2021. Valid till 26.09.2023.
	Evidence of approval of manufacturing facility	Firm has submitted copies of inspection reports indicating steroid injectable section. **Section approval letter is not submitted.**
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7348 dated 15.03.2022
	Details of fee submitted	PKR 75,000/- Slip No. 04405995401 dated 20.01.2022
	The proposed proprietary name / brand name	**P-Kort 25mg suspension for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains Prednisolone acetate…..25mg
	Pharmacotherapeutic Group of (API)	Glucocorticoids ATC Code: H02AB06
	Pharmaceutical form of applied drug	Not submitted.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Zhejiang Xianju Pharmaceutical Co. Ltd., Xianyao Road, Xianju, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No: X3-191005 tested on 01.2019 (COA is of Zhejiang Xianju pharmaceutical Co. ltd. And rest of the documents are of Farmabios Italy.)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. **Batches:** P031-181201, P031-181202, P031-181203
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Batches: TB-101 (01.2019), TB-102(06.01.2020), TB-103 (08.01.2020)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Test Product: P-Kort Injection Reference Product: Prednisolone Deltaslab Injection No other details given.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Xianju Pharmaceutical Co. Ltd., Xianyao Road, Xianju, Zhejiang, China.
API Lot No.	
Description of Pack (Container closure system)	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T-101	T-102	T-103
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	01.2019	01.2019	01.2019
Date of Initiation	01.2019	01.2019	01.2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	A copy of registration letter is submitted where K-Cort 40mg/ml injection is registered vide Reg. No. 034395 having triamcinolone acetonide as its active.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval (steroid injection vial) is required.
2.	-	The RRA reference mentioned is discontinued. Valid RRA reference is required.
3.	-	• AD Attested invoices and clearance documents of both drug substances are required. • Valid GMP certificate and manufacturing authorization of API manufacturer issued by relevant regulatory body is required.
4.	3.2.S.4.3	In testing method validation, under heading of detection of impurities of prednisolone, the chromatogram time stamped as 1.2.2019 12:33:56 pm is exactly same as the one given in real time stability studies of batch T-101 acquired for Standard P. kort TB101, TB102, TB103. Why your own chromatogram is copy pasted on a paper having letter head of drug substance manufacturer (M/s Farmabios Italy) whose raw material is not even used in this drug product. Actual data of impurity profiling and drug substance analysis by the drug substance manufacturer is required.
5.	3.2.P.2	• What is use of finished drug product in comparative analysis of calibration curve? Why a calibration curve generated by using test product and reference product? • A figure of drug release profile comparison is submitted. Detailed procedure and media used for drug release profile comparison is required. • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required.
6.	3.2.P.2	As per drug release certificate, following tests are not performed; i. Uniformity of dosage units

		ii. Particle size iii. Sterility iv. BET v. Assay Why drug release is mentioned in drug release certificate? Justify
7.	3.2.P.3.5	Why batch numbers are same as that of product L-Caine and M-kort? Why unique batch numbers are not allotted to each product?
8.	3.2.P.5	The analytical methods (assay and other tests) are totally different from USP. The solvent system, method of preparation of sample, column etc are all different. Justify why USP monograph is not followed.
9.	3.2.P.8	• Clear description of drug product is required, including pharmaceutical form, appearance etc. • The values of pH measured on different time points for all three trial batches are same. Justification is required. • Accelerated stability data is not submitted.
10.		**General Remarks:** The discrepancies in submitted data does not support scientifically the manufacturing, testing and performance of stability studies of trial batches.

Decision of 331st RB: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Copy of section approval (steroid injection vial) is required.	The firm has submitted their response vide letter No. nil dated 18.12.2023 Copy of section approval letter No. 2-4/98-Lic(Pt-I) dated 07.06.2022 I submitted wherein Injection vial/ampoule (steroid) section is mentioned.
2.	-	The RRA reference mentioned is discontinued. Valid RRA reference is required.	Firm has not submitted valid RRA reference. Reference of product of M/s DMS Chemical Pharmaceutical Inc Ltd Shanghai China is submitted.
3.	-	• AD Attested invoices and clearance documents of both drug substances are required. • Valid GMP certificate and manufacturing authorization of API manufacturer issued by relevant regulatory body is required.	Copy of invoice No. XJWH181002OPLPK dated 02.10.2018 attested by AD I & E DRAP Karachi on 23.10.2018 is submitted. Copy of GMP certificate of M/s Zhejiang Xianju Taizhou Zhejiang China is submitted.
4.	3.2.S.4.3	In testing method validation, under heading of detection of impurities of prednisolone, the chromatogram time stamped as 1.2.2019 12:33:56 pm is exactly same as the one given in real time stability studies of batch T-101 acquired for Standard P. kort TB101, TB102, TB103. Why your own chromatogram is copy pasted on a paper having letter head of drug substance manufacturer (M/s Farmabios Italy) whose raw material is not even used in this drug product.	The firm has stated that *"During making copy of documents printer take multiple pages and printed the content of pages on one page. That is why data of one page printed on other page"*

		Actual data of impurity profiling and drug substance analysis by the drug substance manufacturer is required.	
5.	3.2.P.2	• What is use of finished drug product in comparative analysis of calibration curve? Why a calibration curve generated by using test product and reference product? • A figure of drug release profile comparison is submitted. Detailed procedure and media used for drug release profile comparison is required. • Details of reference product including batch No. mfg date, exp date, manufacturer and pictorial evidence of product is required.	**No response is submitted for first 2 points in 3.2.P.2** The firm has submitted copy of invoice of product Prednisolone Deltalab injection Imported 5 ampoules. Purchased from kausar medico Karachi.
6.	3.2.P.2	As per drug release certificate, following tests are not performed; i. Uniformity of dosage units ii. Particle size iii. Sterility iv. BET v. Assay Why drug release is mentioned in drug release certificate? Justify	The firm has stated that "The reference product and the drug product in pharmaceutical equivalence has been tested as per USP monograph. The drug release certificate include all the tests included uin USP monograph. Copy of USP monograph is attached as reference.".
7.	3.2.P.3.5	Why batch numbers are same as that of product L-Caine and M-kort? Why unique batch numbers are not allotted to each product?	The firm has stated that they have corrected the batch numbers.
8.	3.2.P.5	The analytical methods (assay and other tests) are totally different from USP. The solvent system, method of preparation of sample, column etc are all different. Justify why USP monograph is not followed.	The firm has stated that they have updated the method of analysis as per USP monograph. The chromatograms submitted again appear edited and copy pasted.
9.	3.2.P.8	• Clear description of drug product is required, including pharmaceutical form, appearance etc. • The values of pH measured on different time points for all three trial batches are same. Justification is required. • Accelerated stability data is not submitted.	The firm has stated that product is made of 1ml printed glass vail packed in printed unit carton. The firm has state that, *"During compilation of CTD by mistake the pH of the drug product was forgotten to set the entries according to the analytical reports of the drug product"*
10.		**General Remarks:** The chromatograms submitted with the reply appear edit. The reply of the firm is not satisfactory.	

Decision: The board deferred the case for submission of candid and justifiable response by the firm for mentioned observations.

1774.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 1 Sector 25, Korangi Industrial Area, Karachi..**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 1 Sector 25, Korangi Industrial Area, Karachi. DML No. 000933

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate dated 18.11.2021 issued on basis of inspection conducted on 17.11.2021 is submitted. GMP certificate is valid till 16.11.2023
	Evidence of approval of manufacturing facility	Copy section approval letter vide No. 2-9/2014 Vol-I) dated 07.06.2021 is submitted. Tablet General Section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 10645 dated 27.04.2023
	Details of fee submitted	PKR 75,000/- Slip No. 66842064464 dated 13.03.2023
	The proposed proprietary name / brand name	**UPADAGET ER 15mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Upadacitinib hemihydrate equivalent to Upadacitinib ……..15mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA44
	Pharmaceutical form of applied drug	Yellow colored, oblong shaped film coated tablet plain on both sides.
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	10’s, 20’s, 30’s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	RINVOQ Upadacitinib 15mg Tablet Extended release MHRA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Mankind Research Centre, Plot No.: 145, Sector-7, IMT Mansera, Gurugram, Haryana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general

		properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. UDT21001717203
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months. Batch No. UDT/21/0012/122/02, UDT/21/0013/122/02, UDT/21/0014/122/02
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Upadaget ER Tablets 15mg Batch No. 059DS02 Mfg. 13.05.2022 Exp. 13.05.2024 **Reference product:** Rinvoq Tablets 15mg, Batch No. 1171955. mfg.: 22.03.2022, Exp. 22.05.2025 manufactured by M/s AbbVie, Ireland. Pictorial evidence is submitted. **Tests done**: physical characteristics, Hardness, average weight, Identification, Assay, dissolution, uniformity of dosage unit, total impurities. **CDP:** **At pH 1.2**: F2 = 70 **At pH 4.5:** F2 = 76 **At pH 6.8:** F2 = 70 The dissolution profile of both test and reference product are comparable in 3 above mentioned simulated physiological buffer systems.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Mankind Research Centre, Plot No.: 145, Sector-7, lMT Mansera, Gurugram, Haryana, India.
API Lot No.	UDT21001717203 (1001717203)
Description of Pack (Container closure system)	Alu-Alu blister packed in a unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	059DS01	059DS02	-
Batch Size	5000 Tablets	5000 Tablets	-
Manufacturing Date	11.05.2022	13.05.2022	-
Date of Initiation	03.06.2022	03.06.2022	-
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License to manufacture drugs for the purpose of examination test and analysis is submitted, valid till three years from 2.07.2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Upadacitinib** Batch No.: UDT/21/0017/172/03 Mfg date: 06.2021 Exp date: 06.2022 Quantity: 236 grams Invoice No.: - Invoice date: 23.08.2021 Cleared by AD I&E Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	GMP certificate of drug substance is not submitted. Further the copy of License of drug substance manufacturer mentions that it's for manufacturing of drugs for the purpose of examination, test and analysis. Does drug substance manufacturer not hold license to manufacture upadacitinib for commercial use ?	The firm vide letter No. RAQR/ 447/1023 dated 18.10.2023 has stated that M/s Mankind is R&D facility of Shree Jee Laboratories Pvt. Ltd. The commercial manufacturing of APIs, developed by M/s Mankind will be carried out at M/s Shree Jee Laboratories Pvt. Ltd. Located at C-24 & 25, RIICO Industrial Area, Sotanala, Behror district, Alwar, Rajasthan. India The firm has submitted copy of valid GMP certificate of M/s Shree Jee Laboratories Pvt. Ltd. India.

Decision of 331st meeting of the RB: The Board deferred the case for resubmission of complete data of stability and Product development based on data of batches manufactured by using drug substance from GMP certified source, which can be used in commercial batches, along with fee for registration of new drug product.

The firm M/s Getz Pharma (Pvt) Ltd. has submitted their response vide letter No. RA-PV/559/1223 dated 28.12.2023 in compliance to the decision of 331st meeting of the Registration board. The firm has submitted revised Module 3. The details are given below;

Fee and Date of Submission of Reply	Dy No. 108 dated 01.01.2024. Fee Rs. 75000/- submitted vide slip No. 642856928782 dated 29.12.2023
Name and address of API manufacturer.	M/s Jiangxi LongLife Bio-Pharmaceutical Co. Ltd. 198 Industrial Avenue, Jinxian Industrial Park, Nanchang, Jiangxi China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. Z835-13-220801
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months. Batch No. TP-20200423-D01-TP05-01, TP-20200423-D01-TP05-02, TP-20200423-D01-TP05-03
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Upadaget ER Tablets 15mg Batch No. 059DS03 Mfg. 11.04.2023 Exp. 11.04.2025 **Reference product:** Rinvoq Tablets 15mg, Batch No. 1171955. mfg.: 22.03.2022, Exp. 22.05.2025 manufactured by M/s AbbVie, Ireland. Pictorial evidence is submitted. **Tests done**: physical characteristics, Hardness, average weight, Identification, Assay, dissolution, uniformity of dosage unit, total impurities. **CDP:** **At pH 1.2**: F2 = 63 **At pH 4.5:** F2 = 67 **At pH 6.8:** F2 = 64 The dissolution profile of both test and reference product are comparable in 3 above mentioned simulated physiological buffer systems.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Jiangxi LongLife Bio-Pharmaceutical Co. Ltd. 198 Industrial Avenue, Jinxian Industrial Park, Nanchang, Jiangxi China.
API Lot No.	Z835-13-220801
Description of Pack (Container closure system)	Alu-Alu blister packed in a unit carton.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	059DS04	059DS03	-
Batch Size	5000 Tablets	5000 Tablets	-
Manufacturing Date	11.04.2023	11.04.2023	-
Date of Initiation	20.04.2023	20.04.2023	-
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. Gan20200011 dated 02.04.2022 valid till 06.09.2025, issued by Jiangxi Drug Administration China is submitted.
3	Documents for the procurement of API with approval from DRAP (in case of import).	**Upadacitinib hemihydrate** Batch No.: Z835-13-220801 Mfg date: 26.12.22 Exp date: 25.12.24 Quantity: 300grams Invoice No.: 23ATGZ011-012 Invoice date: 23.03.2023 Cleared by AD I&E Karachi.
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1775.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals Plot No. 204, St. No. 1, I-10/3, Islamabad**
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals Plot No. 204, St. No. 1, I-10/3, Islamabad DML No. 000479

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	**New section**
	Evidence of approval of manufacturing facility	Section approval letter of Dry powder for injection (General) vide No. 1-18/90-Lic (Vol-III) dated 21.02.2023 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22145 dated 08.09.2023
	Details of fee submitted	PKR 30,000/- Slip No. 63119211507 dated 29.08.2023
	The proposed proprietary name / brand name	**OPRIME 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Omeprazole as sodium……..40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC01
	Pharmaceutical form of applied drug	A white to off white powder, filled in 10cc transparent tubular glass vial with gray rubber stopper and purple flip off seal placed in transparent tray and packed in unit carton.
	Reference to Finished product specifications	Innovator Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole Sandoz IV (127835) TGA Australia Approved.
	For generic drugs (me-too status)	Risek IV 40mg Reg. No. 024170 M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 2303901
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 1709901, 1607901, 1704901
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Oprime 40mg Injection Batch No. OPT3 **Reference product:** Risek 40mg, Batch No. B.038PA5. mfg.: 08.2022, Exp. 08.2024 manufactured by M/s Getz Pharma Karachi. Pictorial evidence is submitted. **Tests done:** Physical appearance, pH, BET, Sterility test, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	2303901		
Description of Pack (Container closure system)	A white to off white powder, filled in 10cc transparent tubular glass vial with gray rubber stopper and purple flip off seal placed in transparent tray and packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	**Accelerated: 0, 3, (Months)** **Real Time: 0, 3, (Months)**		
Batch No.	OPT1	OPT2	OPT3
Batch Size	800 vials	800 vials	800 vials
Manufacturing Date	04.2023	04.2023	04.2023
Date of Initiation	11.05.2023	11.05.2023	11.05.2023
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New Section
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 3-26/2019-Addl. Dir (QA&LT-I)-56 dated 22.08.2022 issued by DRAP Islamabad is submitted. Valid till 13.06.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA Locally purchased from M/s Vision Pharma
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.S.6 & 3.2.S.7	In container closure system of drug substance, it mentioned that it is of Aluminium. In stability studies summary sheets, glass vial with rubber stopper and aluminium seal is mentioned. Clarify this difference between container closure system of drug substance.
2.	3.2.S.5	Why test of liquid particle count neither included in specifications of drug product nor performed on finished drug product? justify
3.	3.2.P.8	Stability studies data of only 3 months is submitted, complete stability studies data of 6 months is required.

Decision of 331st RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.6 & 3.2.S.7	In container closure system of drug substance, it mentioned that it is of Aluminium. In stability studies summary sheets, glass vial with rubber stopper and aluminium seal is mentioned. Clarify this difference between container closure system of drug substance.	The firm vide letter No. nil dated 13.12.2023 has provided response of drug substance manufacturer i.e. M/s Vision Pharmaceuticals. The drug substance manufacturer has submitted following statement; *"We have used glass vial as primary container for stability study, instead of aluminium container as specified in section 3.2.S.6 (container Closure System), to verify its long term behaviour in final fill container. Retained samples of each lot kept in aluminium container."*
2.	3.2.S.5	Why test of liquid particle count neither included in specifications of drug product nor performed on finished drug product? justify	The firm vide letter No. nil dated 13.12.2023 has stated that they have performed liquid particle count test on drug substance, as it is only ready to fill. The firm has further stated that from now on they will perform this test on finished product regularly. Report of latest test is attached.

3.	3.2.P.8	Stability studies data of only 3 months is submitted, complete stability studies data of 6 months is required.	6th Month stability data is provided.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1776.	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1305-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.206764738781 Dated 27/12/2021
	The proposed proprietary name / brand name	Estresto 50 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 24.3 mg Valsartan ----------25.7 mg
	Pharmaceutical form of applied drug	Violet color, Oblong shape, plain on both side, film coated tablet
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 50 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 24.3/25.7mg tablet of M/s Getz Parma, Karachi. Registration No.093110
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.

	Name and address of API manufacturer.	**Sacubitril & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Valsartan:** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Sacubitril Sodium:** Stability study conditions (Zone IVb). Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24

		months 0, 3, 6, 9, 12, 18, 24 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **Valsartan:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Savesto 50mg tablet of Getz Pharma, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Savesto 50 mg tablet, batch No. 007FB2 by Getz Pharma in Acid media (pH 1.0-1.2), Acetate buffer (PH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-50-ST-001	EST-50-ST-002	EST-50-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone Huangyan Taizhou, Zhejiang, China, attested by AD (I & E), DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23
2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23

		in the analytical method of the drug product manufacture are not the same.	
3.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it was a mistake and has submitted correct report vide letter No. HB/0039/DRAP/PEC/23
4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.
6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.** **Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th RB meeting: Keeping in view the request of the firm, the Registration Board further extended time for submission of shortcomings within a period of 6 months of finalization of minutes of this meeting.

Remarks of Evaluator;

The firm vide letter No. HB/007/DRAP/PEC/24 dated 22.01.2024 has submitted revised information in compliance to decision of 330th meeting of the Registration Board along with new fee. The evaluation of submitted data is given below;

	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.

	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1316-R & I, Dated 23.01.2024
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.035219299196 Dated 01.02.2024
	The proposed proprietary name / brand name	Estresto 50 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril …… 24.3 mg Valsartan ……25.7 mg
	Pharmaceutical form of applied drug	Violet color, Oblong shape, plain on both side, film coated tablet
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 50 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 24.3/25.7mg tablet of M/s Getz Parma, Karachi. Registration No.093110
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate valid till 03.07.2024
	Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system

		and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 12211-221202
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. 12200-180402, 12200-180403, 12200-180404
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	**Test product:** Estresto 50mg Tablets, batch No. ST-004, Mfg 05.2023, exp 05.2025. **Reference product:** Savesto 50mg Tablets, Batch No. 068FB2, manufactured by M/s Getz Pharma Pakistan. **Tests done:** Description, identification, DT, Assay, Dissolution, Impurities. **CDP:** **F2 at pH 1.2:** 73.21, 86.22 **F2 at pH 4.5:** 88.63, 72.94 **F2 at pH 6.8:** 73.61, 91.84
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. China.
API Lot No.	12211-221202
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-50-ST-004	EST-50-ST-005	EST-50-ST-006
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	05.2023	05.2023	05.2023
Date of Initiation	14.07.2023	14.07.2023	14.07.2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. Zhe 20050431 dated 17.06.2020 valid till 16.06.2025 issued by FDA Zhejiang China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Valsartan-Sacubitril Sodium** **Batch No.:** 12211-221202 **Mfg Date:** 22.12.2022 **Quantity:** 3.5Kg **Invoice No.:** 20230320-1 **Invoice Date:** 20.03.2023 **Cleared by:** AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1777.	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1306-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.6954377589 Dated 27/12/2021
	The proposed proprietary name / brand name	Estresto 100 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 48.6 mg Valsartan ----------51.4 mg
	Pharmaceutical form of applied drug	Oval shaped, pale-yellow colored, film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 100 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 49/51mg tablet of M/s Getz Parma, Karachi. Registration No.093111
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.
	Name and address of API manufacturer.	**Sacubitril Sodium & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in

		house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Valsartan:** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Sacubitril Sodium:** Stability study conditions (Zone IVb). Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months 0, 3, 6, 9, 12, 18, 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **Valsartan:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Uperio 100mg tablet (Batch No. TAY84) of Novartis Pharma (Pakistan), Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand in Acid media (pH 1.0-1.2), Acetate buffer (PH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.		
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-100-ST-001	EST-100-ST-002	EST-100-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone Huangyan Taizhou, Zhejiang, China, attested by AD (I & E), DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23
2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given in the analytical method of the drug product manufacture are not the same.	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23
3.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it was a mistake and has submitted correct report vide letter No. HB/0039/DRAP/PEC/23
4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.

6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.** **Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th RB meeting: Keeping in view the request of the firm, the Registration Board further extended time for submission of shortcomings within a period of 6 months of finalization of minutes of this meeting.

Remarks of Evaluator;

The firm vide letter No. HB/007/DRAP/PEC/24 dated 22.01.2024 has submitted revised information in compliance to decision of 330th meeting of the Registration Board along with new fee. The evaluation of submitted data is given below;

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1778	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale

		☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1317-R & I, Dated 22.01.2024
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.25717986600 Dated 01.02.2024
	The proposed proprietary name / brand name	Estresto 100 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril …… 48.6 mg Valsartan ……51.4 mg
	Pharmaceutical form of applied drug	Oval shaped, pale-yellow colored, film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 100 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 49/51mg tablet of M/s Getz Parma, Karachi. Registration No.093111
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate valid till 03.07.2024
	Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance. Batch No. 12211-221202
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. 12200-180402, 12200-180403, 12200-180404
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	**Test product:** Estresto 100mg Tablets, **Reference product:** Savesto 100mg Tablets, Batch No. 026FB3, manufactured by M/s Getz Pharma Pakistan. **Tests done:** Description, identification, DT, Assay, Dissolution, Impurities. **CDP:** **F2 at pH 1.2:** 83.67, 89.26 **F2 at pH 4.5:** 90.39, 78.43 **F2 at pH 6.8:** 72.96, 79.036
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. China.		
API Lot No.	12211-221202		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-100-ST-004	EST-100-ST-005	EST-100-ST-006
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	05.2023	05.2023	05.2023
Date of Initiation	14.07.2023	14.07.2023	14.07.2023

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. Zhe 20050431 dated 17.06.2020 valid till 16.06.2025 issued by FDA Zhejiang China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Valsartan-Sacubitril Sodium** **Batch No.:** 12211-221202 **Mfg Date:** 22.12.2022 **Quantity:** 3.5Kg **Invoice No.:** 20230320-1 **Invoice Date:** 20.03.2023 **Cleared by:** AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1778.	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer l ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1307-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.718801025572 Dated 27/12/2021
	The proposed proprietary name / brand name	Estresto 200 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 97 mg Valsartan ----------103 mg

	Pharmaceutical form of applied drug	Oblong shaped, light-pink colored, film coated tablet, break-line on one side, other side plain, no irregularity.
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 200 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 97/103mg tablet of M/s Getz Parma, Karachi. Registration No.093112
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.
	Name and address of API manufacturer.	**Sacubitril Sodium & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance **<u>Valsartan:</u>** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**<u>Sacubitril Sodium:</u>** Stability study conditions (Zone IVb). <u>Real time:</u> 30°C ± 2°C / 75% ± 5%RH for 24 months 0, 3, 6, 9, 12, 18, 24 months. <u>Accelerated:</u> 40°C ± 2°C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **<u>Valsartan:</u>** Stability study conditions: <u>Real time:</u> 30°C ± 2°C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. <u>Accelerated:</u> 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Uperio 200mg tablet (Batch No. THU47) of Novartis Pharma (Pakistan), Karachi by

		performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand in Acid media (pH 1.0-1.2), Acetate buffer (PH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.		
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-100-ST-001	EST-100-ST-002	EST-100-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone Huangyan Taizhou,

		Zhejiang, China, attested by AD (I & E), DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23
2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given in the analytical method of the drug product manufacture are not the same.	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23
3.		The run time for Valsartan USP given as 40 minutes in analytical method by the drug substance manufacturer, while the chromatograms for method verification data showed run time around 15-20 minutes. Moreover, retention time of valsartan in method verification chromatograms/data is about 5.5 minutes while the chromatograms for assay determination of valsartan (Batch No.10252-210201) has Retention time of 13.1 minutes.	Firm has stated vide letter No. HB/0039/DRAP/PEC/23 dated 22.06.2023 that analysis was performed according to USP; drug substance manufacturer method claims 40 minutes but USP does not recommend 40 minutes The standard retention time in verification studies is 5.5 minutes updated analysis is attached having same retention time i.e. 5.5 minutes While previous submitted analysis having 13.1 retention time was due to human error & instrumental error. Although both reports having same and satisfactory results.
4.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it's a typographic error and has been corrected

4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.
6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.** **Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th RB: Keeping in view the request of the firm, the Registration Board further extended time for submission of shortcomings within a period of 6 months of finalization of minutes of this meeting.

Remarks of Evaluator;

The firm vide letter No. HB/007/DRAP/PEC/24 dated 22.01.2024 has submitted revised information in compliance to decision of 330th meeting of the Registration Board along with new fee. The evaluation of submitted data is given below;

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1780	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1318-R & I, Dated 22.01.2024
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.0799363203 Dated 01.02.2024
	The proposed proprietary name / brand name	Estresto 200 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 97 mg Valsartan ----------103 mg
	Pharmaceutical form of applied drug	Oblong shaped, light-pink colored, film coated tablet, break-line on one side, other side plain, no irregularity.
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 200 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 97/103mg tablet of M/s Getz Parma, Karachi. Registration No.093112
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate valid till 03.07.2024
	Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure,

		general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 12211-221202
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. 12200-180402, 12200-180403, 12200-180404
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	**Test product:** Estresto 200mg Tablets, **Reference product:** Savesto 200mg Tablets, Batch No. 028FB3, manufactured by M/s Getz Pharma Pakistan. **Tests done:** Description, identification, DT, Assay, Dissolution, Impurities. **CDP:** **F2 at pH 1.2:** 79.843, 75.557 **F2 at pH 4.5:** 78.329, 75.138 **F2 at pH 6.8:** 77.40, 89.919
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. China.
API Lot No.	12211-221202
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		EST-200-ST-004	EST-200-ST-005	EST-200-ST-006
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		05.2023	05.2023	05.2023
Date of Initiation		14.07.2023	14.07.2023	14.07.2023
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. Zhe 20050431 dated 17.06.2020 valid till 16.06.2025 issued by FDA Zhejiang China is submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Valsartan-Sacubitril Sodium** **Batch No.:** 12211-221202 **Mfg Date:** 22.12.2022 **Quantity:** 3.5Kg **Invoice No.:** 20230320-1 **Invoice Date:** 20.03.2023 **Cleared by:** AD I&E DRAP Islamabad.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted	

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1779.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)	M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)	**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.

	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India** . Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg" and name of the product license holder is M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System (SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 20mg/ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13766 dated 02.06.2023.

	Details of fee submitted	PKR 150,000/- vide slip No. 442090369 Dated: 30.09.2022
	The proposed proprietary name / brand name	**DOCESOLE 20mg/ml Concentrate for Infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains: Docetaxel……20mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.
	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 20MG/ML KABI MHRA Approved.
	For generic drugs (me-too status)	Mebrexel 20mg Inj Reg. No. 045608 M/s CCL Pharma Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0058,NN0059, NN0060.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp____date:____, by performing following tests; pH, Assay, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 12 months. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. NN0058, NN0059, NN0060. NN1195-A,
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	In pharmaceutical equivalence only pH, Assay & Particulate matter tests are done for comparison. Why all pharmacopoeial tests are not performed for establishing pharmaceutical equivalence. The Reference product specifications mentioned are IP, why comparison is not done with a product having USP specifications as your product are as per USP specifications. Further address of manufacturer and expiry date of reference product are also required.
3.	3.2.P.8	Stability studies data for full shelf life claimed is required.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.

Decision of 333rd meeting: Deferred for submission of reply to above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Notarized Letter of Authorization is required.	The firm vide letter No nil dated 19.12.2023 has submitted copy of notarized Authorization letter.
2.	3.2.P.2	In pharmaceutical equivalence only pH, Assay & Particulate matter tests are done for comparison. Why all pharmacopoeial tests are not performed for establishing pharmaceutical equivalence. The Reference product specifications mentioned are IP, why comparison is not done with a product having USP specifications as your product are as per USP specifications. Further address of manufacturer and expiry date of reference product are also required.	The firm has submitted results of Pharmaceutical equivalence studies with product Taxotere Batch No. 6F286A manufactured by M/s Sanofi Aventis Deutschland GmbH Germany. Now firm has submitted comparison of impurities also.
3.	3.2.P.8	Stability studies data for full shelf life claimed is required.	Stability studies data for shelf life upto 24 months is submitted.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.	Supporting data is submitted.

Decision: Approved as per policy of inspection of manufacturer abroad.

1780.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)	M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)	**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg/ml" and name of the product license holder is

		M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System (SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 80mg/4ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13162 dated 29.05.2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 457189188 Dated: 30.09.2022
	The proposed proprietary name / brand name	**DOCESOLE 80mg/4ml concentrate for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml vial contains: Docetaxel……80mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.

	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 80MG/4ML KABI MHRA Approved.
	For generic drugs (me-too status)	Mebrexel 80mg Inj Reg. No. 045606 M/s CCL Pharma Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0062,NN0063, NN0061.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp____date:____, by performing following tests; pH, Assay, Particulate matter.

	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 12 months**. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. NN0061, NN0062, NN0063. NN2152-B,
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	Pharmaceutical equivalence of product having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.
3.	3.2.P.3.5	Process validation of strength 120mg/6ml is submitted. Validation studies of 80mg/4ml strength are required.
4.	3.2.P.8	Stability studies data for full shelf life claimed is required.
5.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.

Decision of 333rd meeting: Deferred for submission of reply to above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Notarized Letter of Authorization is required.	The firm vide letter No nil dated 19.12.2023 has submitted copy of notarized Authorization letter.
2.	3.2.P.2	Pharmaceutical equivalence of product	The firm has stated that product is

		having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.	same for all strengths, only fill volume is different that's why they have performed pharmaceutical equivalence with one strength only. The firm has requested to consider the same.
3.	3.2.P.3.5	Process validation of strength 120mg/6ml is submitted. Validation studies of 80mg/4ml strength are required.	The firm has stated that same testing method is used for analysis of different strengths that's why same process validation studies are submitted in dossiers of different strengths.
4.	3.2.P.8	Stability studies data for full shelf life claimed is required.	Stability studies data for shelf life up to 24 months is submitted.
5.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.	Supporting data is submitted.

Decision: Approved as per policy of inspection of manufacturer abroad.

1781.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)	M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)	**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg/ml" and name of the product license holder is M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied

		formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System (SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 80mg/4ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13161 dated 29.05.2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 6438456057 Dated: 30.09.2022
	The proposed proprietary name / brand name	**DOCESOLE 120mg/6ml concentrate for infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 6ml vial contains: Docetaxel……120mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.
	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**

	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 120MG/6ML KABI MHRA Approved.
	For generic drugs (me-too status)	Doxetal 120mg/6ml Inj Reg. No. 092154 M/s Rotex Pharma
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0064,NN0065, NN0066.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp____date:____, by performing following tests; pH, Assay, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 12 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. NN0064, NN0065, NN0066.
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	Pharmaceutical equivalence of product having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.
3.	3.2.P.8	Stability studies data for full shelf life claimed is required.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.

Decision of 333rd meeting: Deferred for submission of reply to above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Notarized Letter of Authorization is required.	The firm vide letter No nil dated 19.12.2023 has submitted copy of notarized Authorization letter.
2.	3.2.P.2	Pharmaceutical equivalence of product having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.	The firm has stated that product is same for all strengths, only fill volume is different that's why they have performed pharmaceutical equivalence with one strength only. The firm has requested to consider the same.

3.	3.2.P.8	Stability studies data for full shelf life claimed is required.	Stability studies data for shelf life up to 24 months is submitted.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.	Supporting data is submitted.

Decision: Approved as per policy of inspection of manufacturer abroad.

1782.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Mr. Ahmad Aman CNIC 3740611481985
	Name and address of marketing authorization holder (abroad)	M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra. India
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited,** D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. MS. India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. COPP/CERT/ND/132390/2023/11/47980/231380) dated 17.11.2023 valid till 28.09.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "VISOATE I, Diatrizoate Meglumine and Diatrizoate sodium Injection USP 20 ml pack. " and name of the product license holder is M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/ND/119226/2022/11/42260 dated 29.09.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra India having its manufacturing site at same address. Certificate valid till 28.09.2025 As per certificate, last inspection of the manufacturer

		was conducted on 2nd and 3rd September, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted a distribution certificate. The certificate specifies that product license holder i.e. M/s Unijules Life Sciences Ltd has certified M/s Lab Diagnostic System (SMC) Pvt. Ltd as their preferred distributor for the territory of Pakistan. The agreement will be valid till October 2024 The agreement is not notarized.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Eapp Tracking ID:	**Z7N-3R4-LBPS**
	Details of fee submitted	PKR 150,000/- vide slip No. 27441819713 Dated: 25.10.2023
	The proposed proprietary name / brand name	**VISOATE I 20ml Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Diatrizoate Meglumine …….660 mg Diatrizoate Sodium ……. 100 mg Equivalent to Iodine 370 mg/ml
	Pharmaceutical form of applied drug	Radioopaque contrast agent, supplied as sterile, aqueous solution, intended for intravascular administration.
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, high osmolar X-ray contrast media ATC Code: V08AA01
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's. 20ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Could not be verified Discontinued in USFDA
	For generic drugs (me-too status)	Megluphin Inj Reg. No. 108475 M/s Bajwa Pharma Sheikhupura.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Diatrizoic acid:** M/s Justesa Imagen S. A, Avda, San Pablo, 27 E 28823 Coslada, Madrid Spain. **Meglumine:** M/s Eagle Chemical Works Plot No. 29/A, 1st Phase, GIDC VAPI 396 195 Dist. Valsad Gujrat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (5569) (MGM-001/17, MGM-002/17, MGM-003/17) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 60%±5% RH: 48 months (Real time) Batch No. 3.883, 3.884, 3.885 Batch No. 4326, 4327, 4328 Maglumine: MGM-001/14, MGM-002/14, MGM-003/14, Long term for 36 months, at 30℃± 2℃, 65% ±5% RH.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (0223H2301, 0223H2302.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Trazograf 76% Batch No. I0Z23031. EXP 06.2026 mfg 07,2023 manufactured by **Unique Pharmaceutical labs**, by performing following tests; Physical appearance, identification, particulate matter, extractable volume, pH, sterility, BET, free aromatic amine, Iodine and iodide content, Assay. Pictorial evidence is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Diatrizoate meglumine and diatrizoate sodium injection USP in colorless 20 ml USP type I vial with 20 mm bromobutyl rubber stopper and 20 mm aluminium flip off hook seal of navy blue color labeled in unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is

		conducted at 30°C ± 2°C, 75% ± 5% for 36 months. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. 0223C1801, 0223C1901, 0223B2001,
	Therapeutic indications in USFDA.	Diatrizoate Meglumine and Diatrizoate Sodium Solution is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous. Diatrizoate Meglumine and Diatrizoate Sodium Solution may also be used as an adjunct to contrast enhancement is computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of bowel from adjacent organs or areas of suspected pathology

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	-	COPP is required to be legalized.
3.	-	RRA reference provided is discontinued. Valid RRA reference is require.
4.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.

Decision of 333rd meeting of the board: Deferred for submission of reply to above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Notarized Letter of Authorization is required.	Copy is uploaded on eApp
2.	-	COPP is required to be legalized.	Copy is uploaded on eApp
3.	-	RRA reference provided is discontinued. Valid RRA reference is require.	Firm has submitted reference of UROGRAFIN 370 MG IODINE/ML SOLUTION FOR INJECTION AND INFUSION. CIMA Spain Approved.
4.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.	Submitted on eApp.

Decision: Decision: Approved as per policy of inspection of manufacturer abroad.

1783.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Mr. Ahmad Aman CNIC 3740611481985

	Name and address of marketing authorization holder (abroad)	M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra. India
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited,** D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. MS. India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. COPP/CERT/ND/132212/2023/11/48048/231393) dated 24.11.2023 valid till 17.10.2024 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "VISOATE I, Diatrizoate Meglumine and Diatrizoate sodium Injection USP 20 ml pack. " and name of the product license holder is M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/ND/119226/2022/11/42260 dated 29.09.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra India having its manufacturing site at same address. Certificate valid till 28.09.2025 As per certificate, last inspection of the manufacturer was conducted on 2nd and 3rd September, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted a distribution certificate. The certificate specifies that product license holder i.e. M/s Unijules Life Sciences Ltd has certified M/s Lab Diagnostic System (SMC) Pvt. Ltd as their preferred distributor for the territory of Pakistan. The agreement will be valid till October 2024 The agreement is not notarized.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Eapp Tracking ID:	**G43-7VZ-ZM4N**
	Details of fee submitted	PKR 150,000/- vide slip No. 1996863096 Dated: 2023-10-25
	The proposed proprietary name / brand name	**VISOATE G 370mgI/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Diatrizoic acid…….632.3 mg Meglumine……. 159.4 mg Equivalent to Iodine 370 mg/ml
	Pharmaceutical form of applied drug	Radioopaque contrast agent, supplied in 100mL pet bottle for oral administration.
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, high osmolar X-ray contrast media ATC Code: V08AA01
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	100ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	GASTROGRAFIN DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM 66%;10% USFDA Approved.
	For generic drugs (me-too status)	Gastrografin Solution Reg. No. 000700 M/s Bayer Pak (Pvt.) ltd. Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Diatrizoic acid:** M/s Justesa Imagen S. A, Avda, San Pablo, 27 E 28823 Coslada, Madrid Spain. **Meglumine:** M/s Eagle Chemical Works Plot No. 29/A, 1st Phase, GIDC VAPI 396 195 Dist. Valsad Gujrat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (5569) (MGM-001/17, MGM-002/17, MGM-003/17) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time

	studies)	conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 60%±5% RH: 48 months (Real time) Batch No. 3.883, 3.884, 3.885 Batch No. 4326, 4327, 4328 Maglumine: MGM-001/14, MGM-002/14, MGM-003/14, Long term for 36 months, at 30℃± 2℃, 65% ±5% RH.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (0067D2001, 0067B2001, 0067A2001)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Gastrografin Batch No. . EXP ____ mfg manufactured by **Bracco Diagnostic Inc NJ**, by performing following tests; Physical appearance, Minimum fill, pH, identification, Weight per mL, Iodine and Iodide, Microbial test, Assay. Pictorial evidence is not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	100 ml amber colour pet bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is conducted at 30℃ ± 2℃, 65% ± 5% for 36 months. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. 0067A1601, 0067A1701, 0067A1801.
	Therapeutic indications in USFDA.	Diatrizoate Meglumine and Diatrizoate Sodium Solution is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous. Diatrizoate Meglumine and Diatrizoate Sodium Solution may also be used as an adjunct to contrast enhancement is computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of bowel from adjacent organs or areas of suspected pathology

Evaluation by PEC:

Sr. No.	Section	Observation

1.	-	Notarized Letter of Authorization is required.
2.	-	COPP is required to be legalized.
3.	1.5.9	The label applied does not indicate sodium salt. The innovator product uses both sodium salt and meglumine. Label needs to be revised as per innovator product along with submission of fee for pre-registration variation.
4.	3.2.P.2	Batch No. expiry date and mfg date of reference product (Gastrografin) is required. The picture submitted is generic picture of the product, pictorial evidence of actual pack used in pharmaceutical equivalence is required.
5.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.

Decision of 333rd meeting of the board: Deferred for submission of reply to above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	-	Notarized Letter of Authorization is required.	Copy is uploaded on eApp by the firm.
2.	-	COPP is required to be legalized.	Copy is uploaded on eApp by the firm.
3.	1.5.9	The label applied does not indicate sodium salt. The innovator product uses both sodium salt and meglumine. Label needs to be revised as per innovator product along with submission of fee for pre-registration variation.	The firm has stated that the product is DIATRIZOATE SODIUM AND DIATRIZOATE MEGLUMINE SOLUTION USP 370 mg I/ml – 100 ml mentioned on form 5-F as well as on covering letter. In the submitted application and Form 5F, firm has given following label; Diatrizoic acid USP – 632.3 mg Meglumine USP – 159.4 mg
4.	3.2.P.2	Batch No. expiry date and mfg date of reference product (Gastrografin) is required. The picture submitted is generic picture of the product, pictorial evidence of actual pack used in pharmaceutical equivalence is required.	Submitted. Trazogastro Batch No. ATB23007
5.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.	Submitted.

Decision: Approved as per policy of inspection of manufacturer abroad with following label claim;
Each ml contains:
Diatrizoate meglumine…….660 mg
Diatrizoate sodium ……. 100 mg
Equivalent to Iodine 370 mg/ml
Letter shall be issued after submission of fee of Rs. 300,000/- for preregistration variation as per SRO 496(I)/2023 read with SRO 1872(I)/2023 dated 29.12.2023.

1784.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27248 dated 20.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 6080374876 dated 12.08.2022
	The proposed proprietary name / brand name	**NALFORT 10mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Nalbuphine hydrochloride..…… 10mg
	Pharmacotherapeutic Group of (API)	Morphinan derivatives ATC Code: N02AF02
	Pharmaceutical form of applied drug	1ml glass ampoule, containing solution for injection.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of USFDA is discontinued.
	For generic drugs (me-too status)	Kinz 10mg injection Reg. No. 018686 M/s Sami pharmaceuticals Karachi.
	Name and address of API manufacturer.	M/s Micro Orgo-Chem Shed No. C-1/B, LIC Sector GIDC, VAPI, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. MO/NBP/2101

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. MO/NBP/1401, MO/NBP/1402, MO/NBP/1403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Nalfort 10mg Injection, Batch No. NF-001. **Reference product:** Nubain Injection, Batch No. NL2245. Exp. 12.2023 manufactured by M/s Endo Pharmaceuticals. Pictorial evidence is submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Micro Orgo-Chem Shed No. C-1/B, LIC Sector GIDC, VAPI, Gujrat India		
API Lot No.	MO/NBP/2101		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NF-001	NF-002	-
Batch Size	2000 ampoules	2000 ampoules	-
Manufacturing Date	05.2022	05.2022	-
Date of Initiation	05.2022	05.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. S-GMP & GLP/21092920 valid till 14.09.2023 issued by Food and drug control administration Gujrat state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Nalbuphine Hydrochloride** Batch No.: MO/NBP/2101 Mfg date: 03.2021 Exp date: 01.2024 Quantity: 0.25kg Invoice No.: EX/RU/031/21-22 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The product mentioned on fee slip is Relief injection 10mg/ml, applied product is NALFORT 10mg/ml injection. Clarify.
2.	-	The reference of USFDA given is discontinued. Provide valid reference of RRA approval.
3.	3.2.P.2.2	Origin of reference product in pharmaceutical equivalence (Nubain injection) is not clearly mentioned. Further the pictorial evidence does not indicate the batch No.
4.	3.2.P.8	The fill volume applied is 1ml, in stability studies the size of ampoules mentioned is 5ml. Clarify.
5.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The product mentioned on fee slip is Relief injection 10mg/ml, applied product is NALFORT 10mg/ml injection. Clarify.	The firm vide letter No. nil dated 31.01.2024 has submitted that fee voucher was generated by name of Relief injection whereas trial batches were developed by name of Nalfort injection. The firm has requested to consider the brand name as Nalfort Injection.
2.	-	The reference of USFDA given is discontinued. Provide valid reference of RRA approval.	The firm has provided evidence of NUBAIN 10.0mg/ml 1ml ampoule Approved by health Canada.
3.	3.2.P.2.2	Origin of reference product in pharmaceutical equivalence (Nubain injection) is not clearly mentioned.	The firm has submitted that origin of reference product is of Canada.

		Further the pictorial evidence does not indicate the batch No.	
4.	3.2.P.8	The fill volume applied is 1ml, in stability studies the size of ampoules mentioned is 5ml. Clarify.	The firm has stated that fill volume of ampoule is 1.1ml and it was a typographic mistake.
5.	3.2.P.8	Submit copy of executed BMRs of trial batches	Copies are submitted.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1785.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Tablet section (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 18306 dated 20.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 08287098124 dated 09.07.2023
	The proposed proprietary name / brand name	**DESLO 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Desloratadine……5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX27
	Pharmaceutical form of applied drug	Film coated light yellow colour biconvex round tablet in Alu-Alu blister with leaflet pack in unit carton.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DESLORATADINE 5 MG FILM-COATED TABLETS

		MHRA Approved.
	For generic drugs (me-too status)	Alenor 5mg Tablet Reg. No. 053481 M/s Macter International Karachi.
	Name and address of API manufacturer.	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. DSL/002/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. DH-1501, DH-1502, DH-1503.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deslo. **Reference product:** Neo-Antial, Batch No. 003H ____. mfg.: _____, Exp. _____ manufactured by M/s Sami Pictorial evidence not submitted. **Tests done:** Description, dissolution, DT, Average weight, Uniformity of dosage unit & Assay. **CDP:** **pH 1.2:** F2 dissolution above 85% in 15min **pH 4.5:** F2 dissolution above 85% in 15min **pH 6.8:** F2 51%
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.		
API Lot No.	DSL/002/21		
Description of Pack (Container closure system)	Film coated light yellow colour biconvex round tablet in Alu-Alu blister with leaflet pack in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DS-001	DS-002	DS-003
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	01.2022	01.2022	01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. HFW-H (Drugs) 93/91 dated 05.01.2023 valid till 11.05.2024 issued by Health and welfare department Himachal Pradesh state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Desloratadine** Batch No.: DSL/002/21 Mfg date: 10.2021 Exp date: 09.2024 Quantity: 0.25kg Invoice No.: EXP/090018 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neo-Antial) used in pharmaceutical equivalence are not provided.

		Further pictorial evidence of reference product is also required
2.	3.2.P.2	In graphs of CDP, products Lewdes and Clarinex are compared. These products are related to other manufacturers, why are these mentioned here, justify.
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neo-Antial) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm vide letter No. nill dated 31.01.2024 has submitted following details; Batch No. 003H Mfg date: 08.2022 Exp date: 06.2024
2.	3.2.P.2	In graphs of CDP, products Lewdes and Clarinex are compared. These products are related to other manufacturers, why are these mentioned here, justify.	Firm has submitted revised CDP data and have stated that it was a typographic error.
3.	3.2.P.8	Submit copy of executed BMRs of trial batches	Copies are submitted.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1786.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Oral Liquid (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23985 dated 02.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 889855969206 dated 12.09.2023

	The proposed proprietary name / brand name	**DESFORA SYRUP 0.5mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains; Desloratadine……0.5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX27
	Pharmaceutical form of applied drug	A clear colourless syrup with bubble gum flavour
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Desloratadine 0.5 mg/ml oral solution - PL 17907/0502; UK/H/5946/001/DC MHRA Approved.
	For generic drugs (me-too status)	Desora Syrup Reg. No. 055192 M/s SJ&G Fazul Ellahi Karachi.
	Name and address of API manufacturer.	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. DSL/002/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. DH-1501, DH-1502, DH-1503.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Desfora. **Reference product:** Neo-Antial syrup, Batch No. 2518 mfg.: 02.2019, Exp. 01.2021 manufactured by M/s Sami Pictorial evidence not submitted. **Tests done:** Description, identification, filled volume, deliverable volume, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.		
API Lot No.	DSL/002/21		
Description of Pack (Container closure system)	A clear colourless syrup with bubble gum flavour		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	D-001	D-002	D-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	07.12.2021	08.12.2021	09.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. HFW-H (Drugs) 93/91 dated 05.01.2023 valid till 11.05.2024 issued by Health and welfare department Himachal Pradesh state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Desloratadine** Batch No.: DSL/002/21 Mfg date: 10.2021 Exp date: 09.2024 Quantity: 0.25kg Invoice No.: EXP/090018 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Pictorial evidence of reference product used in pharmaceutical equivalence is required.
2.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
3.	3.2.P.2.2	Pictorial evidence of reference product used in pharmaceutical equivalence is required.	The firm vide letter No. nil dated nil has submitted generic picture of Neo-Antial Syrup
4.	3.2.P.8	Submit copy of executed BMRs of trial batches	Submitted.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1787.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23984 dated 02.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 8125522416 dated 12.09.2023
	The proposed proprietary name / brand name	**ARTEFOR 40mg/ml IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Artemether ……40mg

	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain ATC Code: P01BE02
	Pharmaceutical form of applied drug	Clear, colourless or almost colourless oily solution filled in glass ampoule.
	Reference to Finished product specifications	**Ph. Int Specifications.**
	Proposed Pack size	1's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified for 40mg strength.
	For generic drugs (me-too status)	Artem 40mg Injection Reg. No. 050689 M/s Hilton Pharma Karachi.
	Name and address of API manufacturer.	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. AM4N/20210919
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. AM2/20130710, AM2/20130711, AM2/20130712
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Artofer Inj. **Reference product:** Misomal Inj, Batch No. ____. mfg.: _____, Exp. _____manufactured by M/s

		Pfizer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Content uniformity, clarity of solution, particulate matter, Assay, BET and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.		
API Lot No.	PGB03521AL		
Description of Pack (Container closure system)	Clear, colourless or almost colourless oily solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B#A004	B#A005	B#A006
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	26.12.2021	27.12.2021	28.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 25-KD/352 dated 15.12.2021 valid till 31.12.2025 issued by FDA Maharashtra is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Artemether** Batch No.: AM4N/20210919 Mfg date: 09.2021 Exp date: 08.2025 Quantity: 2kg Invoice No.: EXP/090018-21 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

Sr. No.	Section	Observation
1.		Valid and verifiable evidence of RRA approval of applied formulation is required.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.		Valid and verifiable evidence of RRA approval of applied formulation is required.	The firm has submitted reference of Switzerland. **It is not verifiable** Available as additional strength in monograph of International Pharmacopoeia.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm has submitted following details of reference product; Misomal Injection, manufactured by Tabros Pharma. Batch No. 236P. Exp date 04.2023
3.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.	Firm has stated that it was a typographic error. Testing was done at 216nm wavelength.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1788.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17330 dated 11.06.2023
	Details of fee submitted	PKR 30,000/- Slip No. 5537894239 dated 16.06.2023
	The proposed proprietary name / brand name	**ARTEFOR 80mg/ml IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Artemether ……80mg
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain ATC Code: P01BE02
	Pharmaceutical form of applied drug	Clear, colourless or almost colourless oily solution filled in glass ampoule.
	Reference to Finished product specifications	**Ph. Int Specifications.**
	Proposed Pack size	1's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product in WHO EML
	For generic drugs (me-too status)	Artem 80mg Injection Reg. No. 015529 M/s Hilton Pharma Karachi.
	Name and address of API manufacturer.	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. AM4N/20210919
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. AM2/20130710, AM2/20130711, AM2/20130712

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Artofer Inj. **Reference product:** Misomal Inj, Batch No. ____. mfg.: _____, Exp. _____manufactured by M/s Pfizer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Content uniformity, clarity of solution, particulate matter, Assay, BET and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.		
API Lot No.	AM4N/20210919		
Description of Pack (Container closure system)	Clear, colourless or almost colourless oily solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B#A001	B#A002	B#A003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	26.12.2021	27.12.2021	28.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 25-KD/352 dated 15.12.2021 valid till 31.12.2025 issued by FDA Maharashtra is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Artemether** Batch No.: AM4N/20210919 Mfg date: 09.2021 Exp date: 08.2025 Quantity: 2kg Invoice No.: EXP/090018-21 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
3.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm has submitted following details; Misomal Injection manufactured by Tabros Pharma. Batch No. 279P Exp Date: 06.2023
4.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.	The firm has stated that it was a typographic mistake. The analysis was done at 216nm Wavelength.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1789.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24325 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 09288945 dated 15.09.2023
	The proposed proprietary name / brand name	**FORCIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin…… 500mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02
	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Ciproxin 500mg tablet Reg. No. 107222 M/s Bayer Pakistan.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 500mg Tablet. **Reference product:** Ciproxin 500mg Tablet, Batch No. ____. mfg.: _____, Exp. _____ manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:** **pH 1.2:** F2 94.98 **pH 4.5:** F2 95.18 **pH 6.8:** F2 85.49
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021

No. of Batches		3
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.

Decision of 333rd RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided.	Firm has submitted following details Ciproxin Tablet Batch No KH06590 Mfg 10.2019

		Further pictorial evidence of reference product is also required	Exp 09.2024 Pictorial Evidence is also submitted.
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.	The firm has stated that it was due to wrong entry in SAP system. Analysis was done at 276nm wavelength.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?	The firm has stated that according to USP tailing factor and relative standard deviation can also be used for system suitability so they have used these 2 parameters for performance of system suitability.
4.	3.2.P.8	Submit copy of executed BMRs of trial batches	Submitted.
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.	The firm has stated that it is peak of diluent. As evidence firm has provided chromatogram of blank run wherein same peak is present.

Decision: The board deferred the case for submission of justification for deviating from monograph of drug product, comply with the monograph and submit data of test and analysis accordingly.

1790.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24326 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 853539306 dated 15.09.2023
	The proposed proprietary name / brand name	**FORCIP 750mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin…… 750mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02

	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Cipesta 750mg tablet Reg. No. 055949 M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

		analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 750mg Tablet. **Reference product:** Hiflox 750 Tablet, Batch No. ____. mfg.: _____, Exp. _____ manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:** **pH 1.2:** F2 98.61 **pH 4.5:** F2 97.71 **pH 6.8:** F2 97.81
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021

		Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Hiflox) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Hiflox) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm has submitted following details Hiflox Tablet manufactured by M/s Hilton Pharma. Batch No. 1730 Exp 05.2023
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.	The firm has stated that it was due to wrong entry in SAP system. Analysis was done at 276nm wavelength.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?	The firm has stated that according to USP tailing factor and relative standard deviation can also be used for system suitability so they have used these 2 parameters for performance of system suitability.
4.	3.2.P.8	Submit copy of executed BMRs of trial batches	Submitted.
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required.	The firm has stated that it is peak of diluent.

		Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.	As evidence firm has provided chromatogram of blank run wherein same peak is present.

Decision: The board deferred the case for submission of justification for deviating from monograph of drug product, comply with the monograph and submit data of test and analysis accordingly.

1791.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24324 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 1968847012 dated 12.09.2023
	The proposed proprietary name / brand name	**FORCIP 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin…… 250mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02
	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Ciproxin 500mg tablet Reg. No. 107222 M/s Bayer Pakistan.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials

		base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 250mg Tablet. **Reference product:** Ciproxin 250mg Tablet, Batch No. ____. mfg.: _____, Exp. _____ manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:** **pH 1.2:** F2 94.98 **pH 4.5:** F2 95.18

		pH 6.8: F2 85.49
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation

1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.
6.	-	Why batch numbers of all trial batches of different strength are similar, batch numbering should be unique for each batch.

Decision of 333rd meeting: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm has submitted following details Ciproxin 250mg tablet manufactured by M/s Bayer Batch No. BAA442 EXP 07.2026 Pictorial evidence is submitted.
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.	The firm has stated that it was due to wrong entry in SAP system. Analysis was done at 276nm wavelength.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?	The firm has stated that according to USP tailing factor and relative standard deviation can also be used for system suitability so they have used these 2 parameters for performance of system suitability.
4.	3.2.P.8	Submit copy of executed BMRs of trial batches	Submitted.
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.	The firm has stated that it is peak of diluent. As evidence firm has provided chromatogram of blank run wherein same peak is present.

Decision: The board deferred the case for submission of justification for deviating from monograph of drug product, comply with the monograph and submit data of test and analysis accordingly.

1792.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17328 dated 11.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 030692819420 dated 04.07.2023
	The proposed proprietary name / brand name	**CITIFOR 250mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline…… 250mg
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Pharmaceutical form of applied drug	Clear colourless or almost colourless solution filled in glass ampoule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of ANSM France given stands repealed.
	For generic drugs (me-too status)	Sauran 250mg Injection Reg. No. 030297 M/s Siza International Lahore.
	Name and address of API manufacturer.	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CTS-00891020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. CTS-00010215, CTS-00020215, CTS-00030315.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Citifor Inj. **Reference product:** Neuroline Inj, Batch No. ____. mfg.: _____, Exp. _____manufactured by M/s _____ Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Clarity of solution, particulate matter in Injection, Assay, BET & Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India		
API Lot No.	CTS-00891020		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C001	C002	C003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules

Manufacturing Date	01.2022	01.2022	01.2022
Date of Initiation	16.01.2022	16.01.2022	16.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 20021883 dated 03.03.2021 valid till 02.03.2024 issued by Food and drug control administration Gujrat state India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Citicoline Sodium** Batch No.: CTS-00891020 Mfg date: 10.2020 Exp date: 09.2024 Quantity: 7kg Invoice No.: EXP/180522(20-21) Invoice date: 18.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The reference of ANSM France given is repealed. Provide valid reference of RRA approval.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neuroline) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: The Board deferred that case for submission of valid RRA reference of applied product or submission of following as per decidion of 179th meeting of the Authority;

a. **Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.**
b. **Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**
c. **Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.**
d. **Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

1793.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17329 dated 11.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 428167228907 dated 04.07.2023
	The proposed proprietary name / brand name	**CITIFOR 1g/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline..…… 1g
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Pharmaceutical form of applied drug	Clear colourless or almost colourless solution filled in glass ampoule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of ANSM France given stands repealed.
	For generic drugs (me-too status)	Sauran 1g Injection Reg. No. 030296 M/s Siza International Lahore.
	Name and address of API manufacturer.	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CTS-00891020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. CTS-00010215, CTS-00020215, CTS-00030315.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Citifor Inj. **Reference product:** Neuroline Inj, Batch No. ____. mfg.: _____, Exp. _____manufactured by M/s _____ Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Clarity of solution, particulate matter in Injection, Assay, BET & Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India		
API Lot No.	CTS-00891020		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C004	C005	C006
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	01.2022	01.2022	01.2022

Date of Initiation	16.01.2022	16.01.2022	16.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 20021883 dated 03.03.2021 valid till 02.03.2024 issued by Food and drug control administration Gujrat state India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Citicoline Sodium** Batch No.: CTS-00891020 Mfg date: 10.2020 Exp date: 09.2024 Quantity: 7kg Invoice No.: EXP/180522(20-21) Invoice date: 18.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The reference of ANSM France given is repealed. Provide valid reference of RRA approval.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neuroline) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The reference of ANSM France given is repealed. Provide valid reference of RRA approval.	The firm has submitted evidence of SOMAZINE 1g/4ml ampoule SOLUTION FOR INJECTION, CIMA Spain Approved. The reference is verifiable .
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neuroline) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm has submitted following details; Neuroline 1g/4ml manufactured by M/s Medisure Batch No. F339 Exp 05.2023
3.	3.2.P.8	Submit copy of executed BMRs of trial batches	Submitted

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1794.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26294 dated 31.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 646535107796 dated 10.10.2023
	The proposed proprietary name / brand name	**GENTHATE 4.5M.I.U Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium (4.5MIU) eq to Colistin base activity…….150mg
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	Pharmaceutical form of applied drug	Glass vial filled with white to off-white colored lyophilized powder.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLISTIMETHATE SODIUM EQ 150MG BASE/VIAL USFDA Approved.
	For generic drugs (me-too status)	CBA 150 Injection Reg. No. 103783 Imported by Biocare Pharma Lahore.
	Name and address of API manufacturer.	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has

		summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. A1600307
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. A1680475, A1680476, A1680477
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **COlETIC 4.5MIU Inj Batch no. ____ exp. _____. manufactured by _____.** **Tests:** Description, identification, LOD, pH, uniformity of dosage, particulate matter, sterility, BET, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method

		verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.		
API Lot No.	A1600307		
Description of Pack (Container closure system)	Power for solution for injection in Type- I glass vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	250 vials	250 vials	250 vials
Manufacturing Date	10.2022	10.22	10.22
Date of Initiation	04.10.2022	04.10.2022	04.10.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Verifiable from EudraGMP DUNS No. 305814345 & 401172630
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Colistimethate sodium (USP)** Batch No.: A1600307 Mfg date: 03.2021 Exp date: 02.2026 Quantity: 1kg Invoice No.: 21000898 X3 Invoice date: 29.10.2021 Cleared by AD I&E DRAP Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2.	3.2.P.8	Copy of executed BMRs of trial batches are required.

3.	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 19.01.2024 has submitted following details; Colimate 4.5MIU manufactured by M/s MTI Medical Pvt. Ltd. Batch No. CK-001 Mfg date 03.2023 Exp 03.2025
2.	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies are submitted.
3.	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Copy of AD I&E DRAP Islamabad cleared invoice is submitted.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1795.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26293 dated 31.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 41730109 dated 24.10.2023
	The proposed proprietary name / brand name	**GENTHATE 3M.I.U Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains:

		Colistimethate sodium (3MIU) eq to Colistin base activity…….100mg
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	Pharmaceutical form of applied drug	Glass vial filled with white to off-white colored lyophilized powder.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC MHRA Approved.
	For generic drugs (me-too status)	ColimeTHate Inj 3MIU Reg No. 108905 M/s Tabros Pharma Karachi.
	Name and address of API manufacturer.	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CMS2110006
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. CMS1707001, CMS1707002,

		CMS1707003,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **COLETIC 3MIU Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, LOD, pH, uniformity of dosage, particulate matter, free colistin, sterility, BET, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.		
API Lot No.	CMS 2110006		
Description of Pack (Container closure system)	Power for solution for injection in Type- I glass vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	250 vials	250 vials	250 vials
Manufacturing Date	10.2022	10.22	10.22
Date of Initiation	04.10.2022	04.10.2022	04.10.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Verifiable from EudraGMP DUNS No. 305814345 & 401172630
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Colistimethate sodium (USP)** Batch No.: A1600307 Mfg date: 03.2021 Exp date: 02.2026 Quantity: 1kg Invoice No.: 21000898 X3 Invoice date: 29.10.2021 Cleared by AD I&E DRAP Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No.	Section	Observation	Reply
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 19.01.2024 has submitted following details; Colistin 3MIU manufactured by Integrated laboratories PVt. Ltd. Batch No. NB2211-16A mfg. date 11.2022 exp date 10.2024
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies are submitted.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Copy of AD I&E DRAP Islamabad cleared invoice is submitted.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1796.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli

		Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Infusion Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25757 dated 25.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 36362201985 dated 20.10.2023
	The proposed proprietary name / brand name	**Gen-Zole 4mg/5ml Concentrate for solution for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Zolidronic acid as monohydrate…..4mg
	Pharmacotherapeutic Group of (API)	Bisphosphonates ATC Code: M05BA08
	Pharmaceutical form of applied drug	Clear colourless solution filled in glass vial with flip-off seal.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOMETA 4MG/5ML CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	Zoledronic acid Normon 4mg/5ml Injection Reg No. 082059 M/s Merixil Pharma Islamabad (Importer).
	Name and address of API manufacturer.	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 69020422 dated 13.03.2023
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. ZLA/FPR/001/18, ZLA/FPR/002/18, ZLA/FPR/003/18
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Macdronic 4mg/5ml Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay, BET, Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.
API Lot No.	69020422
Description of Pack (Container closure system)	Clear colourless solution filled in glass vial with flip-off seal.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	03.2023	03.2023	03.2023
Date of Initiation	15.03.2023	15.03.2023	15.03.2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. E-1844451/DD/DCA/VSP/2022 dated 02.11.2022 valid till 01.11.2023, issued by Drug control administration Andhra Pradesh India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	_____ Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Macdronic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 02.12.2023 has submitted pictorial evidence of the reference product macdronic 4mg/5ml injection, Batch No. 23004, mfg date: 05.2023 exp: 04.2025. Manufactured by M/s Macter International ltd.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies of BMR of batches T001, T002 and T003.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	The firm has submitted that drug substance is taken loan from M/s Medisave Pharma. Copy of clearance certificate and loan agreement is submitted. Batch No. 69010122 mfg 01.01.2022 exp: 31.12.2024. Invoice No. DP-378/2021-22 cleared by AD I&E DRAP Lahore on 18.03.2022

4	-	The product is a liquid vial (SVP), section approval is of infusion section. Justify.	Firm has submitted letter of issuance of DML vide No. 1-2/2019-Lic dated 14.02.2020, wherein Ampoule section SVP (General) is mentioned.

Decision of 333rd meeting of RB: The Board Defered the case for verification of manufacturing facility for Liquid Vial SVP of the firm M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.

Remarks of evaluator: The firm vide letter No. nil dated 12.02.2024 has submitted reply in response to decision of the Registration Board.

The firm has shared a copy of inspection report for grant of DML, conducted on 12.12.2019. In the inspection report Infusion section is mentioned as SVP General.

In section approval letter, SVP is not mentioned with infusion section.

Decision: The Board deferred the case for verification of manufacturing facility of the firm from Licensing Division.

1797.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13942 dated 05.06.2023 RnI Verified. Dy. No 27659 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 99142294489 dated 17.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime…….500mg With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications

	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 500mg Reg No. 076005 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 500mg Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.		
API Lot No.	CEIV/B2107059		
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	15.09.2022	15.09.2022	15.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Cefipime HCl Sterile USP L-Arginine** Batch No.: CEIV/B2008086 Mfg date: 08.2020 Exp date: 07.2023 Quantity: 100kg Invoice No.: EXP-373 Invoice date: 17.12.2020 Cleared by AD I&E DRAP Islamabad, Material is imported by M/s Shawan Pharmaceuticals and taken loan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided.

		Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision of 333rd meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm has submitted response vide letter dated 19.04.2024 Product Biopime 500mg injection batch No. 113 manufactured by M/s Biorex Pharmaceuticals. As per data submitted in dossier, pharmaceutical equivalence was established against product Maxipime, now firm is claiming that they had performed pharmaceutical equivalence studies against product Biopime.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Submitted.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Submitted vide letter No. nil dated 19.04.2024. The material is taken loan from M/s Shawan Pharma. The batch No. of drug substance used for manufacturing the trial batches as per submitted dossier was CEIV/B2107059. Now the firm has submitted documents for drug substance having batch No. CEIV/B2008086.
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.	The firm has stated that in future they will use different batch Numbers.

Decision: The Board deferred the case for clarification of difference in data submitted in the application dossier and their response dated 19.04.2024

1798.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 13943 dated 05.06.2023 RnI Verified. Dy. No 27660 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 53358171 dated 16.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime…….1gm With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 1g Reg No. 076007 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 1g Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.		
API Lot No.	CEIV/B2107059		
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	16.09.2022	16.09.2022	16.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Cefipime HCl Sterile USP L-Arginine** Batch No.: CEIV/B2008086 Mfg date: 08.2020 Exp date: 07.2023 Quantity: 100kg Invoice No.: EXP-373 Invoice date: 17.12.2020 Cleared by AD I&E DRAP Islamabad, Material is imported by M/s Shawan Pharmaceuticals and taken loan.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision of 333rd meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm has submitted response vide letter dated 19.04.2024 Product Walfipime 1g injection batch No. 049 manufactured by M/s Valor. As per data submitted in dossier, pharmaceutical equivalence was established against product Maxipime, now firm is claiming that they had performed pharmaceutical equivalence studies against product Walfipime
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Submitted.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Submitted vide letter No. nil dated 19.04.2024. The material is taken loan from M/s Shawan Pharma. The batch No. of drug substance used for manufacturing the trial batches as per submitted dossier was CEIV/B2107059. Now the firm has submitted documents for drug substance having batch No. CEIV/B2008086.
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.	The firm has stated that in future they will use different batch Numbers.

Decision: The Board deferred the case for clarification of difference in data submitted in the application dossier and their response dated 19.04.2024		
Deferred cases of Import Registration.		
1799.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/71) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 75 capsules" and name of the product license holder is M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule*

		PICICLIB 100mg Capsule *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules* *Nilotinib 150mg Capsules*
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21293 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 38927334 Dated: 10.04.2023
	The proposed proprietary name / brand name	**PICICLIB 75mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……75mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.
	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 75mg Reg. No. 103786 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility,

		appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ20380)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 75mg Lot No. R93133 manufactured by Pfizer exp date: 08.2018, by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2 only with Ibrance 75mg. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 24 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. GJ80697, GJ80698, GJ80699.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.

2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.

Decision of 333rd meeting of RB: The Registration board deferred the case for submission of
1. comparative dissolution profile (CDP) studies of the applied product with relevant strength of innovator/comparator product at pH 4.5 & 6.8 as CDP at only pH 1.2 with Ibrance 75mg has been performed.
2. The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.	Copy of Notarized letter of authorization is submitted.
2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.	The firm has submitted CDP at 3 physiological pH values. The CDP is done with Ibrance 75mg mfg by Pfizer Australia, Batch No. DC5128. Results are comparable with the innovator product.
3.	-	The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.	The firm has stated that their specifications are equivalent or more stringent then innovator's specifications.

Decision: Approved as per policy of inspection of manufacturer abroad.

1800.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/72) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 100 capsules" and name of the product license holder is

		M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule* *PICICLIB 100mg Capsule* *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules* *Nilotinib 150mg Capsules*
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21294 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 258771594917 Dated: 12.04.2023
	The proposed proprietary name / brand name	**PICICLIB 100mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……100mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.

	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 100mg Reg. No. 103787 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ80653)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 100mg Lot No. R72228 manufactured by Pfizer exp date: 04.2018, by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2 only with Ibrance 100mg. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and

		100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 24 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. GJ80674, GJ80675, GJ80676.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.
2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.

Decision of 333rd RB: The Registration board deferred the case for submission of
1. comparative dissolution profile (CDP) studies of the applied product with relevant strength of innovator/comparator product at pH 4.5 & 6.8 as CDP at only pH 1.2 with Ibrance 100 mg has been performed
2. The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.	Copy of Notarized letter of authorization is submitted.
2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.	The firm has submitted CDP at 3 physiological pH values. The CDP is done with Ibrance 100mg mfg by Pfizer Australia, Batch No. DD6319. Results are comparable with the innovator product.
3.	-	The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.	The firm has stated that their specifications are equivalent or more stringent then innovator's specifications.

Decision: Approved as per policy of inspection of manufacturer abroad.

1801.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/73) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 125 capsules" and name of the product license holder is M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule* *PICICLIB 100mg Capsule* *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules*

		Nilotinib 150mg Capsules
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21295 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 2051718120 Dated: 12.04.2023
	The proposed proprietary name / brand name	**PICICLIB 125mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……125mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.
	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 125mg Reg. No. 103788 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ80651, GJ80652, GJ80657)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 125mg Lot No. S95591, DF8414 & R64950 manufactured by Pfizer by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2, 4.5 & 6.8. Results of test and reference product are comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 24 months**. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. GJ80668, GJ80671, GJ80672.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.

Decision of 333rd RB: Deferred for the submission of
1. Notarized letter of authorization.
2. The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.	Copy of Notarized letter of authorization is submitted.
2.	-	The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.	The firm has stated that their specifications are equivalent or more stringent then innovator's specifications.

Decision: Approved as per policy of inspection of manufacturer abroad.

1802.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No. 000140)**
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s Woodwards Pakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1558 dated 17.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 81335098361 dated 04.01.2023
	The proposed proprietary name / brand name	**ZOOKA 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Cefixime (Compacted)…….400mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	0 size white & purple capsule containing off white powder.
	Reference to Finished product specifications	**JP Specifications.**
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 400mg Capsule USFDA Approved.
	For generic drugs (me-too status)	Cefspan 400mg Capsule Reg. No. 013860

		M/s Barrett Hodgson
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 400mg Capsule **Reference product:** Cefiget 400mg, Batch No. -354. mfg.: 04.2022, Exp. 03.2024 manufactured by M/s Getz Pharma Pictorial evidence is submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 77 **At pH 4.5:** F2 = 84 **At pH 7.2:** F2 = 74
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
API Lot No.	00243/044/2022
Description of Pack (Container closure system)	0 size white & purple capsule containing off white powder.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	5WC400	5WC401	5WC402
Batch Size	75000 capsules	75000 capsules	75000 capsules
Manufacturing Date	05.2022	05.2022	05.2022
Date of Initiation	05.2022	05.2022	05.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local Purchase
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	1.4.3.3	Copy of latest and valid GMP certificate of drug product manufacturer is required.
4.	-	The applied label is of Cefixime compacted 400mg. The salt or hydrate form is not mentioned. Label claim needs to be revised as per innovator product along with requisite fee.
5.	3.2.P.2	CDP is done at pH 1.2, 4.5 and 7.2. Justify doing CDP at pH 7.2 instead 6.8.
6.	3.2.P.2	Batch No and expiry date of reference product (Cefiget) is not mentioned. Also provide pictorial evidence of the reference product.
7.	3.2.P.5	Specifications of JP are applied.

8.	3.2.P.8	Audit trail of HPLC is required.

Decision of 333rd RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Copy of section approval letter of drug product manufacturer is required.	The firm vide letter No. nil dated 15.03.2024 has submitted their response. Copy of section approval letter No. 2-36/85-Lic dated 30.10.2008 is submitted wherein Capsule (Cephalospsorin) Section is mentioned.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.	Copy of certificate issued by DRAP Lahore, valid till 18.11.2024 is submitted (M/s Pharmagen)
3.	1.4.3.3	Copy of latest and valid GMP certificate of drug product manufacturer is required.	Copy of GMP certificate issued on basis of inspection conducted on 20.02.2024 is submitted.
4.	-	The applied label is of Cefixime compacted 400mg. The salt or hydrate form is not mentioned. Label claim needs to be revised as per innovator product along with requisite fee.	Fee of Rs. 7500/- is submitted vide slip No. 07150773861 for revision of label.
5.	3.2.P.2	CDP is done at pH 1.2, 4.5 and 7.2. Justify doing CDP at pH 7.2 instead 6.8.	The firm has stated that as per specifications issued by DRAP, dissolution of capsule is to be done at pH 7.2, that's why they replaced pH 6.8 with 7.2 in CDP studies.
6.	3.2.P.2	Batch No and expiry date of reference product (Cefiget) is not mentioned. Also provide pictorial evidence of the reference product.	Firm has submitted following details; Cefiget 400mg Capsule, batch No. 354 Pictorial evidence is submitted.
7.	3.2.P.5	Specifications of JP are applied.	The firm has attached Notification No. 14-1/2022-PEC dated 14.03.2022 wherein Specifications for specifications of Cefixime capsule were issued as per decision of 313rd meeting of the board.
8.	3.2.P.8	Audit trail of HPLC is required.	The firm has stated that their HPLC software is not CFR 21 compliant. The firm has quoted a case of 307th meeting of Registration board and have stated that a case was approved when the applicant has stated that their HPLC software was not CFR-21 compliant

Decision: Approved with Manufacturers Specification. Letter shall be issued after submission of fee of Rs. 7500/- for revision of specifications.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1803.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No.**

		000140)
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s Woodwards Pakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1556 dated 17.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 9802677893 dated 17.10.2022
	The proposed proprietary name / brand name	**ZOOKA 100mg/5ml Powder for oral suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefixime (as trihydrate)…….100mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 100 mg/5 ml granules for oral suspension (cefixime) - UK/H/5626/001/DC; PL 40168/0005 MHRA Approved.
	For generic drugs (me-too status)	Cefiget Powder for Oral Suspension Reg. No. 045119 M/s Getz Pharma
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 100mg Suspension **Reference product:** Cefiget 100mg/5ml, Batch No. 286. mfg.: 03.2022, Exp. 03.2024 manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, uniformity of dosage unit and assay **CDP:** **At pH 1.2:** F2 = 80 **At pH 4.5:** F2 = 92 **At pH 7.2:** F2 = 74

	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
API Lot No.	00243/044/2022
Description of Pack (Container closure system)	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	4WD100	4WD101	4WD102
Batch Size	6666 bottles	6666 bottles	6666 bottles
Manufacturing Date	04.2022	04.2022	04.2022
Date of Initiation	04.2022	04.2022	04.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	3.2.P.2	Pictorial evidence of the reference product used in pharmaceutical equivalence is required.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.
5.	3.2.P.8	Audit trail of HPLC is required.

Decision of 333rd RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Copy of section approval letter of drug product manufacturer is required.	The firm vide letter No. nil dated 15.03.2024 has submitted their response. Copy of section approval letter No. 2-36/85-Lic dated 30.10.2008 is submitted wherein dry powder (Cephalospsorin) Section is mentioned.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.	Copy of certificate issued by DRAP Lahore, valid till 18.11.2024 is submitted (M/s Pharmagen)
3.	3.2.P.2	Pictorial evidence of the reference product used in pharmaceutical equivalence is required.	Not submitted.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.	Clear copies of chromatograms are submitted.
5.	3.2.P.8	Audit trail of HPLC is required.	The firm has stated that their HPLC software is not CFR 21 compliant. The firm has quoted a case of 307th meeting of Registration board and have stated that a case was approved when the applicant has stated that their HPLC software was not CFR-21 compliant

Decision: Approved

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1804.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No. 000140)**
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s Woodwards Pakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1557 dated 17.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 632691643 dated 17.10.2022
	The proposed proprietary name / brand name	**ZOOKA DS 200mg/5ml Powder for oral suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefixime (as trihydrate)…….200mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200mg/5ml For suspension, Lupin USFDA Approved.
	For generic drugs (me-too status)	Cefiget DS Powder for Oral Suspension Reg. No. 045120 M/s Getz Pharma
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures

		and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 200mg Suspension **Reference product:** Cefiget DS 200mg/5ml, Batch No. _____ mfg.: _____, Exp. _____ manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, uniformity of dosage unit and assay **CDP:** **At pH 1.2:** F2 = 80 **At pH 4.5:** F2 = 92 **At pH 7.2:** F2 = 74
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
API Lot No.	00243/044/2022
Description of Pack (Container closure system)	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	5WD200	5WD201	5WD202
Batch Size	6666 bottles	6666 bottles	6666 bottles
Manufacturing Date	05.2022	05.2022	05.2022
Date of Initiation	05.2022	05.2022	05.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	3.2.P.2	Exactly same data is submitted as that of 100mg/5ml strength. Clarify and provide batch No, mfg date and exp date of reference product used. Pictorial evidence of the reference product used in pharmaceutical equivalence is required.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.
5.	3.2.P.8	Audit trail of HPLC is required.
6.	3.2.P.8	The chromatograms submitted are not readable. The chromatogram images are copy pasted on another page and stretched as an image. Clarify why images of chromatograms are edit. Further submit real chromatograms in the actual form as they are acquired by the system.

Decision of 333rd RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Copy of section approval letter of drug product manufacturer is required.	The firm vide letter No. nil dated 15.03.2024 has submitted their response. Copy of section approval letter No. 2-36/85-Lic dated 30.10.2008 is submitted wherein dry powder (Cephalospsorin) Section is mentioned.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.	Copy of certificate issued by DRAP Lahore, valid till 18.11.2024 is submitted (M/s Pharmagen)
3.	3.2.P.2	Exactly same data is submitted as that of 100mg/5ml strength. Clarify and provide batch No, mfg date and exp date of reference product used. Pictorial evidence of the reference product used in pharmaceutical equivalence is required.	Firm has not submitted complete response against this point. Only picture of Cefiget 200mg/5ml is submitted.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.	Readable cpies of chromatograms are submitted.
5.	3.2.P.8	Audit trail of HPLC is required.	The firm has stated that their HPLC software is not CFR 21 compliant. The firm has quoted a case of 307th meeting of Registration board and have stated that a case was approved when the applicant has stated that their HPLC software was not CFR-21 compliant
6.	3.2.P.8	The chromatograms submitted are not readable. The chromatogram images are copy pasted on another page and stretched as an image. Clarify why images of chromatograms are edit. Further submit real chromatograms in the actual form as they are acquired by the system.	No clarification is submitted regarding copy pasting of chromatograms. Clear copies of chromatograms are submitted

Decision: Decision: Approved
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Deferred Form-5 Cases

1805.	Name and address of manufacturer / Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name +Dosage Form + Strength	MEFLOX 400mg/250ml Infusion
	Composition	Each ml contains; Moxifloxacin HCl……..1.6mg
	Diary No. Date of R& I & fee	Dy.No.16973 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740092 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14

	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	250ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MOXIFLOXACIN 400 MG/250 ML SOLUTION FOR INFUSION - PL 24598/0022; UK/H/4829/001/DC MHRA APPROVED.
	Me-too status	Avelox Infusion Reg. No. 109733 M/s Bayer Pakistan Kot Lakhpat.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator.	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. In pack size, 2 volumes are mentioned (100ml and 250ml). By changing volume amount of drug per infusion changes so different volume needs to be applied separately. iii. The strength in label claim is of combined drug and its HCl. The label needs to be revised to mention equivalent strength of drug as its HCl salt. Requisite for correction is also required (Full Fee)
	Decision of 323rd RB Meeting	**Deferred for submission of correct Form-5 along with correct details of applied product and applicable full fee as per notification No. F.7-11/2012-B&A/DRAP dated 07.05.2021.**
	Remarks of the Evaluator.	The firm vide letter No. CSH/2023/Reg-17 dated 22.01.2024 has submitted that this application please may be considered for 250ml pack size, it was also mentioned on Form-5 on which application was submitted. Firm has submitted copy of Form-5 submitted. Label needs to be standardized as under Each 250ml IV Infusion contains; Moxifloxacin (as hydrochloride)…..400mg
	Decision: Approved with following label; Each 250ml IV Infusion contains; Moxifloxacin (as hydrochloride)…..400mg Letter shall be issued after submission of fee of Rs. 75000/- for preregistration variations..	
1806.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 10mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl…….10mg
	Dairy No. date of R &I fee	Dy. No. 15240 dated 07.03.2019. Fee paid vide voucher No. 0758996 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 10mg/ml Reg. No. 053437 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.

	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of product having similar volume and container in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 47325806 dated 23.02.2023. • Firm has not provided other details, whether it will be ampoule or vial and what will be the volume of the ampoule or vial.
	Decision of 326th RB	**of 326th RB: Deferred for submission of details of container closure system and fill volume.**
	Remark of the Evaluator.	The firm vide letter No. AP/2024/08638 dated 26.01.2024 has submitted following label claim; Each 1ml Ampoule contains; Nalbuphine HCl…..10mg The firm has also submitted fee of Rs. 30,000/- vide slip no. 47325806
	Decision: Approved with following Label; **Each 1ml Ampoule contains;** **Nalbuphine HCl…..10mg**	
1807.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 20mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl…….20mg
	Dairy No. date of R &I fee	Dy. No. 15231 dated 07.03.2019. Fee paid vide voucher No. 0758795 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 20mg/ml Reg. No. 053438 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of product having similar volume and container in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 6610606744 dated 23.02.2023. • Firm has not provided other details, whether it will be ampoule or vial and what will be the volume of the ampoule or vial.
	Decision of 326th RB	**Deferred for submission of details of container closure system and fill volume.**
	Remarks of Evaluator	The firm vide letter No. AP/2024/08638 dated 26.01.2024 has submitted following label claim; Each 1ml Ampoule contains; Nalbuphine HCl…..20mg The firm has also submitted fee of Rs. 30,000/- vide slip no. 6610606744
	Decision: Approved with following label; **Each 1ml Ampoule contains;** **Nalbuphine HCl…..20mg**	
1808.	Name and address of manufacture / Applicant	M/s Alen Pharmaceuticals, Plot No. 138-A, Nowshera Industrial Estate Mardan Road, Risalpur. (Contract Giver) (DML No. 000435). & M/s Bio-Labs (Pvt) Ltd, Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad (Contract acceptor) (DML No. 000296)
	Brand Name + Dosage Form and Strength	Allazole 100mg/50ml I.V Infusion

	Composition	Each 50ml contains: Fluconazole……100mg
	Dairy No. date of R &I fee	Dy.No.16810 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0815832 dated 27.02.2019, endorsed on 06.03.2019
	Pharmacological Group	ANTIMYCOTICS FOR SYSTEMIC USE, Triazole and tetrazole derivatives. ATC Code: J02AC01
	Type of form	Form- 5 (Contract Application)
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluconazole 2mg/ml solution for infusion. 50ml, 100ml, 200ml. MHRA Approved
	Me-too-status	Could not be verified.
	GMP Status	Last GMP inspection was conducted on 05-12-2017 and 06-12-2017. GMP audit performa stated that Liquid Infusion 100ml (General) Section was found GMP compliant. However, GMP certificate was not attached.
	Remark of the Evaluator.	i. Copy of latest GMP inspection report/ certificate of ii. M/s Bio-Labs is required is required. iii. ii. Copy of DML of M/s Alen Pharmaceuticals is iv. required. v. iii. Copy of section approval letter of M/s Bio-Labs is vi. required. vii. iv. Me too reference could not be verified. Proper me viii. too reference is required.
	Decision of 323rd RB	**Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 09.01.2024 has submitted following evidence of me-too product; Influderm 100mg Infusion. Reg. no. 069391 M/s Surge Laboratories. The reference is verifiable.
	Decision: Approved.	
1809.	Name and address of manufacture / Applicant	M/s. Arsons Pharmaceutical Industries, 2.5KM Defence Road, off Multan Road, Lahore. (contract giver) (DML No.000514) Contract with M/s. MeDPharm Research Lab, 28-KM, Ferozepur Road, Lahore. (Contract Acceptor) (DML No.000878) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form and Strength	ARZONE IV Injection 1000mg
	Composition	Each Vial contains; Ceftriaxone as Sodium……1000mg
	Dairy No. date of R &I fee	Dy. No. 16595 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730984 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of form	Form- 5 (Contract Application)

	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 1g Powder for Solution for Injection or Infusion (ceftriaxone sodium) - PL 42671/0001 MHRA Approved.
	Me-too-status	Rocephin IV Inj. Reg. No. 008437 M/s Roche Pakistan Ltd. Karachi.
	GMP Status	Firm has submitted routine GMP inspection report dated 27.10.2022. GMP status is reported as good.
	Remark of the Evaluator.	i Form 5 doesn't mention name of applicant (M/s. arsons Pharma) anywhere. Correct Form 5 along with full fee is required to be submitted. ii The firm vide letter No. MRL/DRA/024/2023 dated 06.01.2023 has stated that they have mentioned name of applicant (M/s Arson Pharma) under heading of "Manufactured for". The firm has submitted copy of annexure of application. The Form-5 submitted was from M/s MedPharm Research Lab.
	Decision of 324th RB	**Deferred for submission of Form 5 from the applicant instead of the drug product manufacturer along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**
	Remark of the Evaluator.	The firm vide letter No. ARS/04/24 dated 02.05.2024 has submitted revised Form-5, but fee is not submitted.
	Decision: Approved. Letter shall be issued after submission of fee for preregistration variation.	
1810.	Name and address of manufacture / Applicant	Standpharm Pakistan (Pvt) Ltd. 20Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form and Strength	VEXNIL-P TABLET
	Composition	Each film-coated tablet contains: Paracetamol……325mg Tramadol Hydrochloride….37.5mg
	Dairy No. date of R &I fee	Dy.No. dated 23-02-2015, Differential fee: Rs. 12,000 Dated 19-02-2015 vide deposit slip No.0308737 dated 19-02-2015. "Duplicate dossier"
	Pharmacological Group	Analgesic
	Type of form	Form- 5
	Finished product specifications	Not Mentioned
	Pack size and Demand Price	10's MRP Rs. 10.0 per tablet
	Approval status of product in Reference Regulatory Authorities	Ultracet coated tablet (Janssen Pharma) US FDA approved. In MHRA both coated and uncoated available.
	Me-too-status	Tramal plus film coated tablet of M/s The Searle Company, Lahore. Registration No. 077129
	GMP Status	cGMP compliance certificate No. 101/2020-DRAP (AD-322072-1295) dated 29-06-2020 issued based on evaluation conducted on 18-02-2020.
	Remark of the Evaluator.	• Firm was asked to submit covering letter, bearing statistical officer and DRAP R & I stamp along with fee challan copy of initial submission but did not provide the same. • Firm has revised finished drug product specifications as per USP and submitted fee Rs:7500/- vide deposit slip No.60091350. Minutes of of 321st meeting of Registration Board (20th -

		22nd September, 2022) 987 • Tablet Section (General) section available as per Licensing Division letter No.F.1-51/84-Lic (Vol-II) dated 30-06-2020 for renewal of Drug Manufacturing License.
	Decision of 321st RB	**Deferred for verification of R & I record of initial submission of registration application and differential fee submission.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 12.01.2024 has submitted their response. The firm has stated that they have submitted fees as under; Rs. 8000/- vide slip no. 15503054, with R&I receiving dated 07.11.2022. Rs. 12000/- vide slip No. 0308737 dated 19.02.2015 R&I 23.02.2015 Firm has submitted yellow slip (customer copy) of the differential fee submitted vide slip No. 0308737 dated 19.02.2015
	Decision: Deferred for verification of fee from concerned division.	
1811.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Oraz 40mg Powder for solution for injection
	Composition	Each vial of powder for solution for infusion contains: Omeprazole Sodium eq. to Omeprazole Sodium…….40mg
	Dairy No. date of R &I fee	Dy.No 8310 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form- 5
	Finished product specifications	Manufacture's specification
	Pack size and Demand Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazol 40mg injection of (MHRA approved)
	Me-too-status	Fymezole Dry Powder Injection IV of M/s Fynk Pharmaceuticals
	GMP Status	Same as above
	Remark of the Evaluator.	• Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1812.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Smep IV 40mg Powder for solution for injection Infusion
	Composition	Each Vial Contains: Esomeprazole Sodium eq to Esomeprazole ……40mg
	Dairy No. date of R &I fee	Dy.No 8312 dated 25-02-2019 Rs.20,000/- Dated 25-02-

		2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form- 5
	Finished product specifications	Manufacture's specification
	Pack size and Demand Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV injection of (USFDA approved)
	Me-too-status	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP Status	Same as above
	Remark of the Evaluator.	• Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1813.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Trupan 40mg Powder for Solution for Injection
	Composition	Each Vial Contains: Pantoprazole as sodium sesquihydrate……40mg
	Dairy No. date of R &I fee	Dy.No 8296 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form- 5
	Finished product specifications	Manufacture's specification
	Pack size and Demand Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Protonix injection of (USFDA approved)
	Me-too-status	Pazole Dry Powder Injection IV of M/s Fynk Pharmaceuticals,
	GMP Status	Same as above
	Remark of the Evaluator.	• Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1814.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad

	Brand Name + Dosage Form and Strength	Artisin 30mg Powder for Injection
	Composition	Each Vial Contains: Artesunate……30mg
	Dairy No. date of R &I fee	Dy.No 8296 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antimalarial
	Type of form	Form- 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too-status	Gen-M Injection of M/s Genix Pharma
	GMP Status	Last GMP inspection was conducted on 21-02-2019 concluded as, "Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good."
	Remark of the Evaluator.	Approval of section/manufacturing facility (Dry powder vial) by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (general) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1815.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Artisin 60mg Powder for Injection
	Composition	Each Vial Contains: Artesunate……60mg
	Dairy No. date of R &I fee	Dy.No 8297 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antimalarial
	Type of form	Form- 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too-status	Misonate 60mg Injection by M/s Tabros Pharma (Reg#057719)
	GMP Status	Last GMP inspection was conducted on 21-02-2019 concluded as, "Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good."
	Remark of the Evaluator.	Approval of section/manufacturing facility (Dry powder vial) by the Central Licensing Board.

	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (general) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1816.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Artisin 120mg Powder for Injection
	Composition	Each Vial Contains: Artesunate……120mg
	Dairy No. date of R &I fee	Dy.No 8298 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antimalarial
	Type of form	Form- 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too-status	Gen-M Injection of M/s Genix Pharma
	GMP Status	Last GMP inspection was conducted on 21-02-2019 concluded as, "Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good."
	Remark of the Evaluator.	Approval of section/manufacturing facility (Dry powder vial) by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (general) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Lyophilized liquid vial for injection section (General) is mentioned.
	Decision: Approved	
1817.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Cetolite Injection 125mg/ml
	Composition	Each ampule of 1ml contains: Citicoline as Sodium…125mg
	Dairy No. date of R &I fee	Dy.No 8301 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics)
	Type of form	Form- 5
	Finished product specifications	Manufacturers specification

	Pack size and Demand Price	2ml x 10"s ; As per SRO
	Approval status of product in Reference Regulatory Authorities	CITICOLINE PANPHARMA 250 mg/ 2 ml, solution injectable (IM,IV) ampoule. ANSM approved
	Me-too-status	CT-Nol of M/s Uni-Tiech Pharmaceutials, (Reg.#047049)
	GMP Status	Same as above
	Remark of the Evaluator.	
	Decision of 295th RB	**Deferred for confirmation of required manufacturing facility / section from Licensing Division.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Ampoule) (general) n section is mentioned.
	Decision: Approved	
1818.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Crystofer Injection 20MG/ML
	Composition	Each 1ml contains: Iron as iron sucrose (iron (III)-hydroxide sucrose complex…….20mg
	Dairy No. date of R &I fee	Dy.No 8533 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Iron replacement product
	Type of form	Form- 5
	Finished product specifications	**USP**
	Pack size and Demand Price	5ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer 100mg/5ml Injection of MHRA approved
	Me-too-status	Bisleri 100mg/5ml Injection of M/S Sami Pharma
	GMP Status	Same as above
	Remark of the Evaluator.	Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Ampoule) (general) n section is mentioned. Label needs to be standardized along with requisite fee.
	Decision: Approved with following label; **Each 5ml ampoule contains;** **Iron as iron sucrose (iron (III)-hydroxide sucrose complex) …….100mg** **Letter shall be issued after submission of fee of Rs. 30,000/-**	
1819.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Mecobal 500mcg Injection

	Composition	Each 1ml contains Mecobalamin…500mcg
	Dairy No. date of R &I fee	Dy.No 8320 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Co-enzyme-type vitamin B12
	Type of form	Form- 5
	Finished product specifications	Manufacture's specification
	Pack size and Demand Price	1ml x 5's, 1ml x10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA Japan approved
	Me-too-status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical,
	GMP Status	Same as above
	Remark of the Evaluator.	Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Ampoule) (general) n section is mentioned. Label needs to be standardized and specifications needs to be reviewed along with requisite fee.
	Decision: Approved with following label; **Each 1ml ampoule contains;** **Mecobalamin…500mcg** **Letter shall be issued after submission of fee of Rs. 30,000/-**	
1820.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Dalofen 25mg/ml Solution for injection or infusion
	Composition	Each ml contains: Diclofenac Sodium…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9670 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	NSAIDS
	Type of form	Form- 5
	Finished product specifications	Manufacture's specification
	Pack size and Demand Price	1ml x 5's, 1ml x10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Econac 75mg/3ml Solution for Injection MHRA Approved AKIS 25mg/ml solution for injection (MHRA Approved)
	Me-too-status	Econac 75mg/3ml Solution for Injection MHRA Approved AKIS 25mg/ml solution for injection (MHRA Approved)
	GMP Status	The firm was inspected on 12-11-2018 & 02-01-2019 and conclusion of inspection was: Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommends the renewal of DML for Crystolite Islamabad for following sections.

		1- Tablet section (gen) 2- Capsule section (gen) 3- Cream/ointment section (gen) 4- Topical lotion section (gen) 5- Cream/Ointment section (steroid) 6- Topical lotion section (steroid) 7- Oral Sachet (gen) 8- Soft gelatin capsule (gen) 9- Syrup section (gen)
	Remark of the Evaluator.	• Letter of deficiencies sent on 09-10-2020 and reminder on 27-01-2021 but no reply received yet • Provide evidence of section approval • Revise the 1st page of form 5 as per prescribed format • You have applied for label claim Each ml contains: Diclofenac Sodium…25mg while you have applied for 3ml volume. Clarify? • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in the applied volume • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III
	Decision of 307th RB	**Deferred for following:** **• Evidence of required manufacturing facility/section approval letter** **• Revision of the 1st page of form 5 as per prescribed format** **• Clarification of label claim as reference formulation** **• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in the applied volume** **• Justification for not performing terminal sterilization** **• Mention type of primary packaging material of applied formulation whether it is type I, II or III**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Ampoule) (general) n section is mentioned. Response to rest of the points mentioned in Decision of 307th meeting of Registration Board are not addressed. Label needs to be standardized and specifications needs to be reviewed along with requisite fee.
	Decision: Approved with following label; **Each 1ml ampoule contains;** **Diclofenac Sodium…25mg** **Letter shall be issued after submission of fee of Rs. 30,000/-**	
1821.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad

	Brand Name + Dosage Form and Strength	Solar-D 5mg/ml Solution IM/Oral.
	Composition	Each ml Contains: Cholecalciferol ……..…5mg (200000IU)
	Dairy No. date of R &I fee	Dy. No 11232 dated 05-03-2019; Rs.20,000/- 05-03-2019
	Pharmacological Group	Vitamin D3 analogue.
	Type of form	Form- 5
	Finished product specifications	Innovator's specifications.
	Pack size and Demand Price	1's & as per DPC
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200,000 IU / 1 ml, oral solution in ampoule VITAMIN D3 GOOD 200,000 IU / 1 ml, solution for injection IM in ampoule, ANSM approved
	Me-too-status	Indrop D Oral Liquid, Neutro Pharma, Reg. No. 071506
	GMP Status	Same as above
	Remark of the Evaluator.	Manufacturing facility/section approval could not be confirmed.
	Decision of 307th RB	**Deferred for confirmation of Manufacturing facility/section approval for the applied formulation.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Ampoule) (general) n section is mentioned.
	Decision: Approved with following label; **Each 1ml ampoule contains;** **Cholecalciferol ……..…5mg (200000IU)** **Letter shall be issued after submission of fee of Rs. 30,000/-**	
1822.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Biovac 500mg Powder for solution for injection.
	Composition	Each Vial Contains: Vancomycin HCl…….500mg (eq to 500,000 IU Vanomycin)
	Dairy No. date of R &I fee	Dy.No 8295 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 500mg Powder for Solution for Infusion of MHRA approved
	Me-too-status	Vancotic 500mg Injection by M/s English Pharm
	GMP Status	Same as above
	Remark of the Evaluator.	Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six**

		months.
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Vial) (general) section is mentioned.
	Decision: Approved.	
1823.	Name and address of manufacture / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Biovac 1g Powder for solution for injection.
	Composition	Each Vial Contains: Vancomycin HCl…….1g (eq to 500,000 IU Vanomycin)
	Dairy No. date of R &I fee	Dy.No 8313 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 1g Powder for Solution for Infusion n of MHRA approved
	Me-too-status	Vancotic 1gm Injection by M/s English Pharm,
	GMP Status	Same as above
	Remark of the Evaluator.	Approval of section/manufacturing facility by the Central Licensing Board.
	Decision of 324th RB	**Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (General) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 22.05.2024 has submitted copy of DML renewal letter No. 1-54/2009-Lic (Vol-I) dated 22.03.2024 wherein Liquid Injectable (Vial) (general) section is mentioned.
	Decision: Approved.	

Case No. 1: Registration of formulations containing Vitamins / Minerals

Deputy Director HOTC Division has forwarded the decision of 116th meeting of Enlistment Evaluation Committee (EEC) held on 23rd May 2023 vide its letter dated 3rd January 2024. As per the letter, EEC issued show cause notice to the firms / companies having enlistment of Vitamin D3 above RDA upto 200,000IU. In response to show cause, various companies submitted their replies / written statement along with documentary evidence in support of their claim, subsequently personal hearing was afforded to such firms. EEC after due deliberation considering the submissions decided to refer back the case to Registration Board for consideration of its decision in the light of publications / submissions made by various firms. Accordingly, submissions of following companies are hereby forwarded for the consideration of RB.

Accordingly, the letter along with submissions of various firms has been forwarded to PE&R Division.

PE&R Division has reviewed the submissions of the firms and no submission contains any evidence of approval in reference regulatory authorities. Moreover, PE&R Division has also checked the status of reference product i.e. Vitamin D3 (cholecalciferol) 200,000IU Capsule in the below mentioned RRA and found that the same is not included as drug.

#	Agency/Country	Website link

1.	USFDA (USA)	https://www.accessdata.fda.gov/scripts/cder/daf/
2.	Health Canada (Canada)	https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
3.	TGA (Australia)	https://compliance.health.gov.au/artg/
4.	PMDA (Japan)	http://www.pmda.go.jp/PmdaSearch/iyakuSearch/
5.	MHRA (UK)	https://products.mhra.gov.uk/
6.	ANSM (France)*	http://agence-prd.ansm.sante.fr/php/ecodex/ https://base-donnees-publique.medicaments.gouv.fr/
7.	DMDI (Germany)	https://portal.dimdi.de/amguifree/am/search.xhtml
8.	CBGMEB (Netherland)	http://www.geneesmiddeleninformatiebank.nl/nl
9.	Swissmedic (Switzerland)	https://www.swissmedicinfo.ch/
10.	AGES (Austria)	https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=53559007139362908&_afrWindowMode=0&_adf.ctrl-state=11ajcl0qd9_4
11.	Denmark	https://www.produktresume.dk/AppBuilder/search
12.	Sweeden	https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta?activeTab=1
13.	Norway	https://www.legemiddelsok.no/
14.	Belgium	http://bijsluiters.fagg-afmps.be/?localeValue=nl
15.	Finland	https://www.fimea.fi/laakehaut_ja_luettelot
16.	Italy	https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/
17.	Ireland	http://www.hpra.ie/
18.	Iceland	https://www.serlyfjaskra.is/
19.	Spain	https://cima.aemps.es/cima/publico/home.html
20.	EMA (Europe)	https://www.ema.europa.eu/en/medicines
21.	WHO	https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

Decision: The board after detailed delibration/discussion, decided that the Vitamin D3 (cholecalciferol) 200,000IU Capsule is not found as drug in the above mentioned RRAs, hence the matter is referred back to the division of Health & OTC, DRAP.

Registration-I Section

Case No.01. Request of M/s Webros Pharmaceuticals, Rawat for Issuance of De-Registration Letter of Products Transferred to M/s Bloom Pharmaceuticals (Pvt) Ltd., Hattar.

Registration Board in its 267th meeting held on 20th-21st February, 2017 approved the request for cancellation of registrations of following products from M/s Webros Pharmaceutical, Plot No. 1, Street No. 10, National Industrial Zone, Rawat (DML No.000538) Rawat and registration of the same in favor of M/s Bloom Pharmaceuticals (Pvt) Ltd. Plot No. 30 Phase I & II Industrial Estate Hattar (DML No.000374)

S.#	Product for registration with generic name	Reg. No.
1	Wenamic Forte Tablet Each tablet contains:- Mefenamic Acid…….500mg	032845
3	Womzol Tablet Each tablet contains:- Albendazole……..200mg	038430
4	Vercid Tablet 100mg Each tablet contains:- Mebendazole……..100mg (USP Spec)	070041
5	Hydroheal Cream Each gram contains:- Hydrocortisone acetate…1%w/w	072054

	(BP Spec)	
6	Webnate Ointment Each gram contains:- Betamethasone as valerate……..…0.1%w/w (BP Spec)	072055
7	Webnate Cream Each gram contains:- Betamethasone valerate…….0.1%w/w (BP Spec)	072056
8	Webnate- N Ointment Each 5gram contains:- Betamethasone valerate…0.1% Neomycin Sulphate……0.5% (BP Spec)	072057
9	Webnate- N Cream Each 5gram contains:- Betamethasone valerate…0.1% Neomycin Sulphate……0.5% (BP Spec)	072058
10	Betaheal Cream Each gram contains: Betamethasone dipropionate……..0.1%w/w	072059

In line with the decision of 267th meeting, registration of following products was issued to M/s Bloom Pharmaceuticals, Hattar vide letter No. F.13-3/2017-Reg-IV-(M-267) dated 13-10-2017. However, till to date cancellation letter has not been issued to M/s Webros Pharmaceuticals, Rawat.

S.#	Old Brand Name of drug (s) & Composition	Old Reg. No.	New Reg. No.	New Brand Name of drug (s) & Composition
I	*II*	*III*	*IV*	*V*
1.	Wenamic Forte Tablet Each tablet contains:- Mefenamic Acid…….500mg	032845	082918	Mefadon Forte Tablet Each film coated tablet contains:- Mefenamic Acid….500mg (BP Specifications)
2.	Vercid Tablet 100mg Each tablet contains:- Mebendazole……..100mg (USP Spec)	070041	082919	Blomeb Tablet 100mg Each tablet contains:- Mebendazole……..100mg (USP Specifications)
3.	Hydroheal Cream Each gram contains:- Hydrocortisone acetate…1%w/w (BP Spec)	072054	082920	Blocon Cream Each gram contains:- Hydrocortisone acetate…1%w/w (BP Specifications)
4.	Webnate Ointment Each gram contains:- Betamethasone as valerate……..…0.1%w/w (BP Spec)	072055	082921	Junate Ointment Each gram contains:- Betamethasone as valerate…..…0.1%w/w (BP Specifications)
5.	Webnate Cream Each gram contains:- Betamethasone valerate…….0.1%w/w (BP Spec)	072056	082922	Junate Cream Each gram contains:- Betamethasone as valerate…….0.1%w/w (BP Specifications)
6.	Webnate- N Ointment Each 5gram contains:- Betamethasone valerate…0.1%	072057	082923	Junate - N Ointment Each gram contains:-

	Neomycin Sulphate……0.5% (BP Spec)			Betamethasone as valerate…0.1% Neomycin Sulphate……0.5% (As per *Innovator's Specifications)
7.	Webnate- N Cream Each 5gram contains:- Betamethasone valerate…0.1% Neomycin Sulphate……0.5% (BP Spec)	072058	082924	Junate - N Cream Each gram contains:- Betamethasone as valerate…0.1% Neomycin Sulphate……0.5% (As per *Innovator's Specifications)

Now, M/s Webros Pharmaceuticals, Rawat has requested to issue letter for de-registration (cancellation) of products mentioned vide *column II* (with their registration numbers in *column III*) of above table stating that these products have already been registered (dated 13-10-2017) in favour of M/s Bloom Pharmaceuticals, Hattar.

Decision: Registration Board acceded to request of M/s Webros Pharmaceuticals, Rawat for De-Registration of above mentioned products (Sr. No 1-7 vide column no. II).

Case No.02. Request of M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan for Consumption of Imported Controlled Drug Substance 'Ketamine Hydrochloride'

Registration Board in its 323rd meeting held on 06th-08th December, 2022 considered the subject mentioned request of M/s Akhai Pharmaceuticals (Pvt) Ltd., A-248 & A-256 to A-259, Hub Industrial Trading Estate Lasbella Balochistan wherein the firm informed that they have been granted registration of **Ketlar (Ketamine) Injection; Reg. No.014966 (valid till 30th June, 2025)** by way of contract manufacturing **at M/s. Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupra Road, Lahore**. The registration was granted for contract manufacturing well before classification of Ketamine under controlled drug substances

Furthermore, M/s Neutro Pharma had imported 50kg of Ketamine Hydrochloride on their behalf and for the exclusive manufacturing of their above stated product. Primary and secondary packaging materials are also available with them. In this context, the firm requested for permission to consume the available quantity of Ketamine Hydrochloride.

However, Ketamine and its salts have been declared as "Psychotropic substances" vide SRO Number 1350(I)/2021 dated 15th October, 2021. Furthermore, as per existing contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021, Rule 20 A 2(c) states that:

"Contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;"

In this context, following comments were also received:

Comments Received from Controlled Drugs Division:

The Committee for Allocation of Quota of Controlled Substances allocates the quota to those firms having valid drug manufacturing license and valid drug registration as per SOP.

Comments Received from QA&LT Division:

Consumption of any API is linked primarily to valid license to manufacture a drug and secondarily to valid registration of that drug. If as a consequence of any change in some rule/regulation or policy the status of both these prerequisite (DML and MA) for any drug becomes void/invalid, the consumption of respective APIs could not be allowed for that particular drug.

Foregoing in view, Registration Board decided as under:

"Keeping in view the classification of "Ketamine and its salts" under psychotropic substances (vide SRO 1350(I)/2021 dated 15th October, 2021) and Rule 20A(2)(c) of Drugs (L, R & A), Rules, 1976, Registration Board decided as follows:

- *Decided to issue show cause notice to the firm under Section 7 (11)(d) of the Drug Act, 1976 that why the registration of their product "Ketlar Injection (Reg. No. 014966)" may not be cancelled. Management of the firm shall also be given the opportunity of personal hearing in the forthcoming meeting of the Board under section 42 of the Drugs Act, 1976.*

- *Recommended QA&LT Division to decided case for already imported material as per Drug (I&E) Rules, 1976."*

Accordingly, show cause and personal hearing notice was issued dated 18-07-2023 and QA&LT Division was communicated the above-mentioned decision, in response to which, Deputy Director (QA/LT) Division has stated as under:

> *"It is pertained to mention that Division of QA & LT is helpless to implement and comply the above decision of Board as Drugs (Import & Export) rules 1976 are silent regarding disposal of this API Ketamine Hcl being Psychotropic material. The import, export, trans-shipment and disposal/destruction of Narcotic/Psychotropic material is governed under Control of Narcotic Substances Act, 1997 in collaboration with Controlled Drug Division of DRAP. It is therefore requested to reconsider the decision and matter may be referred to concerned division for implementation."*

In this context, it is submitted that the field force is under the administrative control of QA&LT Division and regulatory actions could not be carried out without the filed force. Furthermore, Assistant Director (I&E) is also under the administrative control of QA&LT, which is working as Licensing Authority on behalf of CEO, DRAP after delegation of power. Therefore, the fate of imported controlled drug substance "Ketamine" may be decided by QA&LT Division in consultation with Controlled Drugs Division, DRAP and Ministry of Narcotics Control.

Keeping in view the above-mentioned stance of PE&R and QA & LT Division, the case was referred for collective wisdom of the Authority on the matter, please.

DRAP's **Authority in its 173rd meeting held on 10th October, 2023** considered and decided the case as under:

> ***"The request of M/s Akhai Pharmaceuticals was not acceded to as the Drugs (Licensing, Registering & Advertising) Rules, 1976 does not contain the enabling provision to allow contract manufacturing of controlled substance."***

Furthermore, with respect to the show-cause along-with personal hearing notice issued to the firm to appear before the Registration Board on 25th July, 2023 at 2.00 P.M., the case was considered by the Board in its 330th meeting held on 24th-26th July, 2023 wherein no one appeared on behalf of the firm. Accordingly, the Board decided as under:

> ***"Registration Board decided that the firm shall be provided one final opportunity of personal hearing in the next meeting."***

In line with the above-mentioned decision, the firm has been called for personal hearing on 20th December, 2023 at 3:00 P.M.

Proceedings of 333rd Meeting of Registration Board:

While, the meeting was in process, M/s Akhai Pharmaceuticals (vide letter dated 19-12-2023) informed that on 19th December, 2023, they came to know that the case regarding Ketlar Injection has been included in agenda of 333rd meeting. They did not receive the notice of personal hearing yet and no flight is available from Karachi to Islamabad on 20-12-2023. Accordingly, the firm requested to give time for hearing in the next meeting of Registration Board.

Furthermore, Mr. Haroon Dugal, Advocate Supreme Court, as counsel for M/s Akhai Pharmaceuticals also submitted an application for adjournment (received on 20-12-2023) stating that the counsel is representing petitioner in the titled case for which no personal hearing notice has been duly received so far. Furthermore, petitioner's daughter wedding has been scheduled for the same date as the hearing. Accordingly, the petitioner is unable to travel to attend the hearing scheduled on 20-12-2023 as no flight is available from Karachi to Islamabad on the afore mentioned date. Due to the foregoing circumstances, the petitioner will be unable to appear before this Honourable Court. Hence, it is respectfully requested that the case may kindly be adjourned to a date convenient to this Honourable Court in the interest of justice, equity and fair play.

Decision of 333rd Meeting of Registration Board:

Registration Board acceded to the above-mentioned request of M/s Akhai Pharmaceuticals, Balochistan and decided that the firm shall be provided one final opportunity of personal hearing in the next meeting of Registration Board.

In line with the above-mentioned decision, the firm has been called for personal hearing on 06th June, 2024 at 12:00 P.M.

Proceeding 336th meeting:

Mr. Umer Hameed Khan (Advocate High Court) as counsel for M/s Akhai Pharmaceuticals appeared before Registration Board. He admitted the fact that firm has no manufacturing facility of

Psychotropic/narcotic drugs till date, however he requested Board to not cancel the registration of said product till the firm establish its own manufacturing facility.

Registration Board deliberated the matter and opined that firm can't be allowed to continue contract manufacturing of "*Ketlar Injection (Reg. No. 014966)"* in the light of DRAP authority's decision and as per existing contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021, since the firm has no own manufacturing facility for Psychotropic drugs hence registration of said drug deemed cancelled. Moreover, Board has already decided that QA&LT Division in consultation with Controlled Drugs Division, DRAP and Ministry of Narcotics Control will dispose of/destroy already imported API (Ketamine hydrochloride).

Decision: Keeping in view the contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021 and in the light of DRAP authority's decision, Registration Board has decided to cancel the registration of *Ketlar Injection (Reg. No. 014966*) by M/s Akhai Pharmaceuticals and advised QA&LT Division to dispose of/destroy the already imported API (Ketamine hydrochloride) in consultation and coordination with Controlled Drugs Division, DRAP and Ministry of Narcotics Control.

Case No.03. Cancellation of Registrations of Drugs on account of Cancellation of Drug Manufacturing Licenses by Central Licensing Board.

Central Licensing Board in its 293rd meeting held on 20th November, 2023 cancelled the Drug manufacturing licences of following firms:

Sr. No.	Name of Firm	DML No.
1.	M/s Novae Pharmaceuticals, Haripur, Hazara	DML No. 000771 (Formulation)
2.	M/s Swat Pharmaceuticals, Saidu Sharif, Swat	DML No. 000035 (Formulation)
3.	M/s Wahabsons Pharma (Pvt) Ltd., Plot No.402, 4km Bunir Road, Bairkot Swat	DML No. 000533 (Formulation)

In this context, Registration Board in its 307th meeting (held on 08th-10th June, 2021) delegated the function regarding *"Issuance of show cause notice for cancellation of registration after cancellation of DML"* to Chairman Registration Board.

Keeping in view that Chairman Registration Board has been delegated the function regarding *"Issuance of show cause notice for cancellation of registration after cancellation of DML"* as per decision of 307th meeting of Registration Board (held on 08th-10th June, 2021).

Accordingly, show cause notices were issued on 24-01-2024 regarding cancellation of registration in lieu of cancellation of DMLs.

In this regard, following responses have been received from relevant manufacturers:

Name of Registration Holders	Response to Show cause notice issued on 24-01-2024	Dy. No. & Date
M/s Novae Pharmaceuticals, Haripur Hazara (DML No. 000771)	a) Director CLB in 293rd meeting of CLB held on 20-11-2023 directed us to submit shortcomings to Licensing Division within seven days (27-11-2023) b) Detail of shortcomings was: i. Detail of management at the time of previous and present renewal ii. Notarized copy of partnership deed along-with copy of CNICs of all partners iii. Up to date Nothing Due Certificate (CRF) from STO DRAP, Islamabad. c) M/s Novae Pharmaceuticals, Hattar deposited CRF for years 2020,21,22& 23 and applied for issuance of Nothing Due Certificate (CRF) from STO DRAP on 24-11-2023. d) Shortcomings mentioned in para 1b(i-ii) and R&I copy of application submitted for NDC(CRF) along-with deposited slips of respective years were submitted to Secretary, CLB on 25-11-2023.	Dy.No. 2174 dated 31-01-2024

	e) We had received Nothing Due Certificate (CRF) upto year 2023 on 24-01-2024 and the same had been submitted to Secretary, CLB on 30-01-2024 with request for constitution of panel of inspection for renewal of DML at earliest as all the shortcoming have been fulfilled. f) After receiving orders form Dir, QA&LT, DRAP, we M/s Novae Pharmaceuticals had immediately stopped production activities and are preparing for renewal inspection. We M/s Novae Pharmaceuticals hereby undertake and assure your honor that we shall resume production activities after restoration/renewal of DML. Above in view, **it is requested that registration of drugs granted under DML # 000771 may not be cancelled. Moreover, if an opportunity for personal hearing is granted by Registration Board, evidence required if any can be provided at the time of hearing.**	
M/s Swat Pharmaceuticals, Saidu Sharif, Swat (DML No. 000035)	We have challenged the decision (cancellation of DML No 000035) of CLB in Appellate Board. Therefore, **we are requesting to leave our case pending up to the final decision of appellate board.**	Dy.No. 2318 dated 02-02-2024
M/s Wahabsons Pharma (Pvt) Ltd., Barikot Swat (DML No. 000533)	It is stated that the cancellation is unlawful and is done in a completely arbitrary, unjustified and irrational manner and without any lawful authority. Furthermore, it is pertinent to mention here that **there is no section of law in the DRUG Act 1976 and rules framed thereunder which refers that cancellation of Drug Manufacturing License will result in cancellation of the registered products/ Drugs of the company. The entire Drug Act 1976, DRAP Act 2012 and Rules framed thereunder are completely silent regarding this matter.** In the light of above mentioned facts, it is most humbly requested the registration of our products should not be cancelled.	Received via TCS 4765836257

Keeping in view the responses submitted by the firms and in line with section 42 of the Drugs Act, 1976, the relevant firms have been called for personal hearing before the Registration Board on 06th June, 2024 at 12:00 P.M.

Proceeding 336th meeting:

Mr. Umer Hameed Khan (Advocate High Court) as counsel for Swat Pharmaceuticals, Saidu Sharif, Swat. He apprised Registration Board that The Appellate Board in 164th meeting held on 28-03-2024 allowed Swat Pharmaceutical's appeal and constituted a Panel of Inspectors. The Panel inspection yet to be conducted however cancellation of DML has been set aside by the Appellate Board. The DML will be reinstated after the inspection takes place.

Similarly, Mr. Arshad Riaz (CEO) and Zeeshan Ahmad (Regulatory Manager) from M/s Wahabsons Pharma (Pvt) Ltd.,Barikot Swat appeared before the Board. They stated that *The Appellate Board in 164th meeting held on 28-03-2024 created Panel of Experts to inspect the premises of manufacturing facility to ensure all GMPs and other requirements of the Drug Act , Rules and Regulations etc have been complied.*

M/s Novae Pharmaceuticals submitted their stance in writing (without physical appearance before the Board). Wherein they informed that The Appellate Board in 164th meeting held on 28-03-2024 converted cancellation of DML into suspension of DML and directed relevant division to inspect the premises. Accordingly, QA&LT division has constituted panel for inspection and they requested to schedule the inspection visit in the next week.

Decision*:* **Since The Appellate Board in its 164th sitting dated 28th March, 2024 directed to inspect the manufacturing facility of above mentioned firms to ensure all GMPs and other requirements of the Drug Act, Rules and Regulations Hence Board decided to suspend**

the registration of products of above mentioned firms till the final order by CLB or the Appellate Board.

Case No.04. Cancellation/ Revocation of Approval Granted to M/s Mission Pharmaceuticals Pvt Ltd. Karachi for Registration of Elvox Tablet 250mg & Elvox Tablet 500mg

Registration Board in its 327th meeting, held on 13th April, 2023, approved following products in favor of M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super Highway Karachi (DML No. 000809):

Table-I

S. No.	Product Name & Composition	Diary No. & Date	Decision of M-327
1.	Elvox Tablet 250mg Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin Base…250mg	Dy No. 15135: 07-03-2019	**Approved.**
2.	Elvox Tablet 500mg Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin Base….500mg	Dy No. 15146: 07-03-2019	**Approved.**

While processing for issuance of registration letter, it was identified that the firm has already been issued registrations of same formulations in same strength and dosage form. Detail is as under:

Table-II

S. No.	Reg. No.	Name of Drug(s) & Composition
1.	112661	Hemlevo Tablet 250mg Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin ……250mg (USP Specifications)
2.	112662	Hemlevo Tablet 500mg Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin ……500mg (USP Specifications)

Accordingly, the case has been placed before the Board for declaring the approvals of 327th meeting as mentioned in Table-I above as redundant/ disposed of.

Decision: Registration Board considered the case and declared approvals of Elvox Tablet 250mg & Elvox Tablet 500mg (327th meeting) as redundant/ disposed of.

Case No.05. Cancellation/ Revocation of Approval Granted to M/s Medicraft Pharmaceuticals (Pvt) Ltd., Peshawar for Registration of Qutimed 100mg Tablet

Registration Board in its 329th meeting, held on 06th-08th June, 2023, approved following product in favor of M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Industrial Estate, Hayatabad, Peshawar (DML No. 000390)

Table-I

S. No.	Product Name & Composition	Diary No. & Date	Decision of M-329
1.	Qutimed 100mg Tablet Each film coated tablet contains: Quetiapine As Fumarate……100mg	Dy No. 16332: 07-03-2019	Approved.

While processing for issuance of registration letter, it was identified that the firm has already been issued registration of same formulation in same strength and dosage form. Detail is as under:

Table-II

S. No	Reg. No.	Name of Drug(s) & Composition
1.	108754	Med-Qpin Tablet 100mg Each film coated tablet contains: Quetiapine as Fumarate……100mg (USP Specifications)

Accordingly, the case has been placed before the Board for declaring the approval of 329th meeting as mentioned in Table-I above as redundant/ disposed of.

Decision: Registration Board considered the case and declared approval of Qutimed 100mg Tablet (329th meeting) as redundant/ disposed of.

Case No. 06 Request for De-Registration of Syrup Products of M/s Maxitech Pharma Private (Ltd), Karachi.

M/s Maxitech Pharma Private (Ltd), Karachi has requested to de-register syrup products. The firm has informed that in 296th meeting of CLB they surrendered their syrup section, in order to fulfill their market demand, they intend to expand their Tablet and Lotion section.

Decision: Registration Board not acceded to request of the firm since request of surrendering/withdrawing "oral liquid/syrup section" has not been acceded to by CLB (296th meeting).

Case No. 07. Request of M/s Faas Pharmaceuticals (Pvt) Ltd, Karachi for Cancellation of Toll Manufacturing Agreement from M/s Nabiqasim Industries Private Limited, Karachi.

Registration board in its 331st meeting considered following application of M/s **Faas Pharmaceuticals** as under:

	Table-I			
S. No.	**Product Name & Composition**	**Contract manufacturer**	**Diary No. & Date**	**Decision of M-327**
1.	**Nomizil 40mg IV injection** Each Lyophilized Vial contains: Omeprazole as sodium"	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Dy.No 9443 dated 13-04-2022 Rs.75,000/- dated 27-10-2021	**Approved.**

While processing registration letter it came to know that same formulation of firm has already been registered with same brand name as per following details:

S. No	**Reg. No.**	**Name of Drug(s) & Composition**	**Contract manufacturer**	**Registration letter details**
1	096351	Nomizil Injection 40mg IV Each vial contains: Omeprazole Sodium eq. to Omeprazole…….40mg	M/s Nabiqasim Industries Private Limited, Karachi	letter No. No.F.3-3/2019-Reg-I (M-288) dated 19-06-2019

Now the firm requested to cancel registration of above mentioned product since they have canceled contract manufacturing agreement from M/s Nabiqasim Industries Private Limited, Karachi, due to market comparative rates.

Decision: Registration Board called the firm for personal hearing regarding its request.

Case No 08: Show Cause Notice to M/s Lisko Pakistan Ltd for Submitting Application of Zinkrol Syrup (Zinc Sulphate Monohydrate Eq To Elemental Zinc….20mg) Twice

M/s Lisko Pakistan Ltd, L-10-D Block 21, Industrial Federal B Area, Karachi has applied two applications for registration of same product which were considered in different meetings details as under:

Extract of M-276	
Name and address of manufacturer / Applicant	M/s Lisko Pakistan, Karachi
Brand Name +Dosage Form + Strength	Zinkrol Syrup 20mg/5ml
Composition	Each 5ml contains: Zinc sulphate monohydrate eq to elemental zinc….20mg
Diary No. Date of R& I & fee	**Dy. No.1226; 31-12-2015; Rs.20,000/- (29-12-2015)**
Pharmacological Group	Zinc Suplement
Type of Form	Form-5
Finished product Specification	International pharmacopoeia
Pack size & Demanded Price	60ml; Rs.80/-

	90ml; Rs.100/- 100ml; Rs.110/- 120ml; Rs.130/-
Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
Me-too status	Zevro Syrup 20mg
GMP status	Last inspection report 23-1-2017 overall GMP compliance level is good.
Remarks of the Evaluator.	
Decision: Approved	

Extract of M-285

Sr. No	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price /Pack size	Approval status in Reference regulatory agencies / authorities Me-too status/ GMP status	Previous Decisions	Evaluation by PEC
380.	M/s Lisko Pakistan Pvt. Ltd. L- 10-D, Block no. 21, Shaheed Rashid Minhas Rd. F.B industrial area, Karachi 346	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate as Elemental Zinc ……..20 mg Zinc Supplement. (Mfg. Specs)	Form5 **31-12-2013** Dy.No.623 Routine Rs. 20,000/- Rs.75/60ml Rs.130/120ml	WHO recommended formulation Zincat oral solution of M/s Atco Labs Karachi (Reg # 053094) GMP inspection conducted on 27-09-2018 concluded that all relevant activities in process areas, QC and ware house were found at good level of GMP compliance. Area FID vide letter No.F.SAA.02-06/2018-FID-V dated 30-08-2018 has confirmed that firm has purchased two stability	Deferred in **262nd** meeting as formulation is under review. Deferred for the confirmation of valid DML status (Drug manufacturing License) from Licensing Division. **(M-282)**	The firm has submitted that the policy regarding formulation of said product has been decided and registration of same has been given to many companies in recent times.

				chambers with capacity of 250L (accelerated) and 800L (Real time), placed in their QC department.		
Decision: Approved with USP specifications.						

Accordingly, registration letters were issued to both products as per following details:

Sr.No	Reg.No.	Brand Name & Composition	Reference Letter No & Dated
1.	092905	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate eq. to Elemental Zinc ……..20mg (USP Specifications)	No.F.3-8/2018-Reg-II (M-285) dated 08-02-2019
2.	086949	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate eq. to Elemental Zinc ……..20mg (IP Specifications)	No.F.3-13/2017-Reg-II (M-276) dated 15-03-2018

Show cause notice to be issued to M/s Lisko Pakistan Ltd for submitting two different applications of same formulation (same strength and same dosage form) i.e Zinkrol syrup 20mg/5ml (zinc sulphate monohydrate).

Decision: Registration Board deliberated the case and decided to issue show cause notice to the firm under Section 7 (11)(a) of the Drug Act, 1976 that why the registration of their product "Zinkrol Syrup (Reg. No. 092905)" may not be cancelled.

Registration-II Section

Case No. 01: Report on Assessment and Confirmation of Manufacturing Capacity of M/s. Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2 RCCI, Rawat (DML No. 000897)

Reference No: F.5-1/2023-Reg-II (M-323) (Misc.)

Inspection Date: 20th March, 2023.

Background: The inspection was conducted on 20.03.2023 in compliance to letter of Assistant Director (Reg-II) vide No.5-1/2023-Reg-II(M-323) (Misc.) dated 07.02.2023

Composition of Panel:

i. Muneeb Ahmed Cheema, Deputy Director PE&R, DRAP Islamabad.
ii. Adil Saeed, Deputy Director PEC-IX, DRAP Islamabad.

Scope of Inspection:

The inspection was conducted for assessment and confirmation of manufacturing capacity of M/s Cure Laboratories (Pvt) Ltd, Plot # 11-12, Street # NS-2, RCCI, Rawat for following sections;

i. Dry Powder Injection (Cephalosporin).
ii. Dry Powder Suspension (Cephalosporin).
iii. Capsule (Cephalosporin).

Manufacturing record/data of last Quarter of 2022 **(1st September 2022 to 31st December 2022)** and 1st Quarter of year 2023 (**1st January, 2023 to March, 2023 till date**) was evaluated for aforementioned purpose. The details of capacity calculations are as under:

Registered Products

	Dry Powder Injection (Cephalosporin) Section	Dry Powder Suspension (Cephalosporin) Section	Capsules (Cephalosporin) Section	Total
Total registered products of manufacturer	41	17	13	71
Registered Products on Contract from the manufacturer	Nil	02	01	03
Total	41	19	14	74

A. CAPACITY OF DRY POWDER FOR INJECTION (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
41	Nil	Nil	11

STEP WISE CAPACITY OF EACH PROCESS				
	Process/Step 1: **Vial Washing**	**Process/step 2: Depyrogenation Capacity**	**Process / step 3: Filling and Sealing Capacity**	**Process/ Step 4: Packing Capacity**
Per day (8 hours working shift)	21,600 Vials	18,000 Vials	21,600 Vilas	30,000 Vials
Per month (22 working days)	475,200 Vials	396,000 Vials	475,000 Vials	660,000 Vials

Capacity calculated with respect to the depyrogenation being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	175,083 vials	1,425,000	12.3%
3rd (1st July- 30th sept 22)	213,837 vials	1,425,000	15%
4th (1st Oct – 31st Dec 22)	178,933 vials	1,425,000	12.6%
1st (1st Jan – 31st March 2023)	140,575 vials	1,425,000	9.9%
Average Capacity Utilized			12.45%

Manufacturing Capacity Utilized (average): 12.45%
Manufacturing Capacity Available (average): 87.55%

B. CAPACITY OF DRY POWDER FOR SUSPENSION (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
17	Nil	02	06

STEP WISE CAPACITY OF EACH PROCESS				
	Process/Step 1: **Bottle Blowing**	Process/step 2: **Mixing**	Process / step 3: **Filling**	Process/ Step 4: **Packing**
Per day (8 hours working shift)	14,400 Bottles	200 Kg	16,800 Bottles	30,000 Bottles

Per month (22 working days)	316,800 Bottles	4400 Kg	369,600 Bottles	660,000 Bottles

Capacity calculated with respect to the Bottle Blowing being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	45,682 bottles	1,108,800	4.12%
3rd (1st July- 30th sept 22)	31,031 bottles	1,108,800	2.8%
4th (1st Oct – 31st Dec 22)	44,438 bottles	1,108,800	4%
1st (1st Jan – 31st March 2023)	79,730 bottles	1,108,800	7.2%
Average Capacity Utilized			4.53 %

Manufacturing Capacity Utilized (average): 4.53%
Manufacturing Capacity Available (average): 95.47%

C. CAPACITY OF CAPSULE (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
13	Nil	01	02

STEP WISE CAPACITY OF EACH PROCESS				
	Process/Step 1: **Mixing**	**Process/step 2: Filling**	**Process / step 3: Blistering**	**Process/ Step 4: Packing**
Per day (8 hours working shift)	100kg	172,800	24,000 Strokes 03 Blisters/Stroke	40,000
Per month (22 working days)	2200kg	3,801,600	528,000	880,000

Capacity calculated with respect to the filling being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	45,411 capsules	11,404,800	0.4%
3rd (1st July- 30th sept 22)	295,455 caps	11,404,800	2.6%
4th (1st Oct – 31st Dec 22)	79,299 caps	11,404,800	0.7%
1st (1st Jan – 31st March 2023)	88,309 caps	11,404,800	0.8%
Average Capacity Utilized			1.125%

Manufacturing Capacity Utilized (average 1.125%
Manufacturing Capacity Available (average): 98.875%

D. CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details		
S.No	Equipment	Quantity
1.	HPLC	02
2.	UV Spectrophotometer	01
3.	pH Meter	01
4.	Polarimeter	01
5.	Dissolution Apparatus	01
6.	Balance	01
7.	Moisture analyzer	01
8.	Cold Incubator	01

9.	Hot Incubator	01
10.	Stability Chamber (Accelerated)	01
11.	Stability Chamber (Real time)	01
12.	Glass Filtration Assembly	01
13.	S.S Filtration Assembly	01

1. HPLC Capacity Calculation
Quarter Wise(Maximum 4 tests/day)TOTAL No of HPLC= 2

QUARTER	Average Capacity of HPLC	Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	264	84	31.81	68.19
2nd (1st May – 30st July 22)	264	59	22.34	77.66
3rd (1st Aug – 31st Oct 22)	264	95	35.98	64.02
4th (1st Nov – 31th Jan 23)	264	65	24.62	75.38
			Average capacity Available:	**71.31%**

2. Capacity Calculation for sterility testing
Quarter Wise (Average 5 tests/day)

Quarter	Capacity	Test Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	330	41	12.42	87.58
2nd (1st May – 30st July 22)	330	20	6.06	93.94
3rd (1st Aug – 31st Oct 22)	330	32	9.69	90.31
4th (1st Nov – 31th Jan 23)	330	54	16.36	83.64
			Average capacity available:	**88.86%**

3. Bacterial Endotoxin Test Capacity Calculation
Quarter Wise (Average 8 tests / day)

Quarter	Capacity	Test Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	528	53	10.03	89.97
2nd (1st May – 30st July 22)	528	22	4.16	95.84
3rd (1st Aug – 31st Oct 22)	528	47	8.91	91.09
4th (1st Nov – 31th Jan 23)	528	116	21.94	78.06
			Average capacity available:	**88.74%**

Ms. Maria Burki Plant Manager/ Production Incharge, Mr. Tasawar Hussain Shah QC Manager and Mr. Umair Aslam QA Manager assisted during the inspection. The details are given below;

1. Raw Material Store:

The raw material store of cephalosporin facility was inspected in detail and following observations were noted.

i. Humidity of RMS at time of inspection was 64% and HVAC system was not operational, which was turned on during inspection.

ii. Boxes of some materials were checked randomly (e.g. Cefixime micronized batch CFEM220042, Cefixime compacted batch CFEC220097 and Magnesium stearate) and it was observed that the poly bags were not sealed to protect the material from environmental factors.

iii. Containers of Cefixime micronized (batch CFEM220042, analysis No. RM0024/QC/API/23 GRN No. 01278) and Cefixime compacted (batch CFEC220097, analysis No. RM0023/QC/API/23 GRN No. 01278) did not contain label of manufacturer. In QC their analysis documents were checked and found that they both were released for use on UV analysis rather HPLC testing which is pharmacopoeial requirements. The firm produced a COA of M/s Covalent Laboratories India of aforesaid API's but couldn't provide their clearance documents.

iv. There was discrepancy between entries of dispensing log book and raw materials stock registers. Some entries in dispensing log book were missing. The storage and documentation practices of the firm for raw materials were found very poor.

2. Production Area:

a. Dry Powder Injection:

The section was not operational at the time of inspection. The production Incharge described the manufacturing process which includes:

i. Vial washing with de-ionized water.
ii. Loading in DHS for sterilization. After sterilization they were
iii. Transfer to filling line through HEPA fitted trolley for filling and capping.

It was noted that firm is using deionized water for final rinsing of vials rather WFI. Moreover, the batch size was not standardized and it was observed that the firm is manufacturing multiple strengths of finished product having different batch numbers and batch sizes as per market demand while using single API container.

b. Dry Suspension:

The section was not operational at the time of inspection. In dry suspension area 200kg mixer was present and again it was observed that batch size was not standardized. Biodroxil 125mg batch No. 23010 was of 7734 units and batch No. 22029 was of 3703 units. Some batches were so small that their mixing in a 200kg mixer is not possible. Humidity of the area was not controlled.

c. Capsule:

The section was not operational at the time of inspection. There was no hygrometer in mixing area. The capacity of mixer in capsule section was 100kg. Again the batch size was not standardized. Roxykef 500mg Capsule batch 22023 had a size of 5607 capsules and batch No. 22003 of same product had a size of 47546 capsules. The mixture to fill 5607 capsules was approximately equal to 3.3kg. Mixing of material of 3.3kg in 100kg mixer is not possible and when it was inquired during inspection the firm informed that they are performing manual mixing in poly bags for such small batches.

There was only one pharmacist looking after all 3 sections of cephalosporin facility and also dispensing of raw materials.

3. In-process quarantine:

There was no in-process quarantine area in cephalosporin manufacturing facility. Quarantine area was established in Finished Goods Store (FGS). In quarantine area following observations were noted;

i. Unlabelled filled vials were present in various boxes. The boxes had labels indicating Vakxon 500mg IM injection batch No. 22115 manufactured in November 2022.
ii. Unlabelled filled vials were also present in other boxes which even did not bear labels. The firm claimed that these are ceftriaxone vials of above batch however they couldn't establish their identity.
iii. Unlabelled dry suspension bottles were also present in boxes having aluminium caps mentioning Herbion. The boxes had labels indicating Biodroxil Suspension 200mg/5ml

Upon inquiry the firm informed that above mentioned unlabelled filled products were placed in quarantine due to the shortage of labelling and packaging material. However as per QC record these batch were passed for release to the market.

4. Finished Goods Store:

The FGS was located in basement of the manufacturing facility. It was common for whole facility.

5. Packing material store:

The foils used for blistering were placed in uncontrolled environment and their polybags were not closed.

6. Quality Control:

a. Main Quality Control Lab:

The firm had 2 HPLC systems and one UV-Vis spectrophotometer. The firm did not had following instruments which are necessary for testing of products being manufactured:

i. FTIR
ii. Liquid particle Counter (LPC)
iii. TOC analyser

b. Microbiology Lab:

The firm had an established microbiology laboratory. Betalactamase enzyme, ATCC strains, LAL test lysate etc were present. Air particle counter was also available.

It was also noted that firm was releasing the API for manufacturing and finished products in the market on UV testing only. Two stability chambers were available for accelerated and real time stability studies of finished products. In accelerated stability chamber, samples of Biodroxil 200mg/5ml were available, the aforesaid product was registered in year 2022 in name of M/s Herbion Pharma Islamabad for contract manufacturing by the firm. The firm informed that they are conducting the accelerated and real time stability on request of registration holder, however on the other side without completion of study for six months the

same product was manufactured on continuous basis and huge stock for market release was available in FGS.

7. Water System:

The firm had double RO system connected with ion exchange cartridges. Firm also had water distillation system but it was not functional. Firm was using deionized water for washing of vials and final rinse of equipment used in sterile manufacturing. Hot loop was not present.

Recommendations & Conclusion:

Keeping in view the above practices, following is being recommended by the panel;

i. Immediate sampling of finished products specifically cephalosporin injectable products available with the firm and released in market.
ii. Panel GMP inspection as it was observed that since grant of DML in 2019, no panel GMP inspection has been conducted so far.
iii. Improvement in raw material storage and documentation practices.
iv. Standardization of batch sizes with process validations.
v. Hiring of at least three more pharmacists to supervise manufacturing and dispensing activities.
vi. Installation of water distillation system for bulk WFI.
vii. Provision of in-process quarantine area in cephalosporin manufacturing facility
viii. Installation of FTIR, TOC analyzer and LPC in QC lab.
ix. Installation of hygrometers and improvement of environmental controls.

Despite of the fact firm possess sufficient manufacturing and testing capacity, however keeping in view the storage, documentation, production and testing practices of the firm recorded above, the panel **DO NOT RECOMMEND** to allow contract manufacturing till the compliance of above recommendations and their verification.

Decision of 329th meeting:

Registration Board on basis of the findings of above presented inspection report decided to defer the registration applications of contract manufacturing from M/s. Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2 RCCI, Rawat till any further decision. Moreover, Registration Board decided to refer the above inspection report to QA&LT Division for further necessary action.

As per above decision of the Board, above mentioned capacity assessment report of M/s. Cure Laboratories was referred to QA &LT Division and said Division has forwarded GMP Inspection report conducted on 23-09-2023 with conclusion as under:

The establishment M/s Cure Laboratories Pvt Ltd situated at Plot No. 11 & 12 Street No. NS-2, RCCI, Rawat was inspected in the light of Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976 and GMP guidelines QALT/GL/MP/004.

In view of above stated facts and observations; by adopting the risk-based approach, it has been unanimously concluded by the panel that GMP is a continual process of improvements and some areas of improvements have been described in the above report. The firm should submit a comprehensive CAPA to the division of Quality Assurance and Lab Testing followed by the verification of CAPA by panel of inspector/experts to ensure the implementations. Overall rating of the firm was concluded to be at a Good level of GMP compliance as of today.

Decision: **Registration Board, on the basis of GMP inspection report, decided to allow issuance of registration letters of all products approved by way of contract manufacturing from M/s. Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2 RCCI, Rawat.**

The Board further decided that QA & LT Division shall include the manufacturing & testing capacity of all sections approved by Central Licensing Board in the GMP inspection of the firms.

Case No. 02: M/s. Davis Pharmaceutical Laboratories, Islamabad

Registration Board in its 329th meeting has approved following drug product in the name of M/s Davis Pharmaceutical Laboratories, 121, Industrial Triangle Area, Kahuta Road, Islamabad,

Sr. No.	Name of Drug & Composition
1.	Davigest Tablet 10mg Each film coated tablet contains:

	Dydrogesterone……10mg USP Specification

While processing registration letter of above said product it is revealed that firm does not have approval of requisite manufacturing facility of Tablet (Hormone) Section. Accordingly, case was referred to Licensing Division for confirmation of approval status of Tablet (Hormone) section and said Division has replied that M/s. Davis does not possess formal approval of the Tablet (Hormone) Section.

Decision: **Registration Board decided to dispose of the said application of M/s Davis Pharmaceutical Laboratories, 121, Industrial Triangle Area, Kahuta Road, Islamabad for registration of Davigest Tablet 10mg (Dy. No. 15937 dated 04-03-2019) as not approved as firm does not possess approval of the Tablet (Hormone) Section by the Central Licencing Board.**

Case No. 03: M/s. Wilson's Pharmaceuticals 387-388 Sector I-9 Industrial Area Islamabad.

cGMP inspection of M/s. Wilson's Pharmaceuticals 387-388 Sector I-9 Industrial Area Islamabad was conducted dated 20-02-2024 to check manufacturing and testing facilities. Federal Inspector of Drugs-IV has referred following observations as mentioned in inspection report for immediate attention at the end of Registration Davison.

Since the renewal of DML does not have Penicillin and Cephalosporin section however the registration of these products either needs to be withdrawn by the management under intimation to this office / referred to the competent authority for its suspension / cancellation.

The establishment also didn't have hormonal section but hold the registration of Estrogen tablet 0.625mg (Reg. No. 011152) and Estrogen tablet 1.25mg (Reg. No. 011153). Which is need to be suspended till the establishment of section.

FID further stated that the case may please be considered for suspension / cancellation of registration of products in Cephalosporin, Penicillin and Hormone Oral Section due to non-availability of the sections.

It is submitted that as per available record of PE&R Division, firm holds registration of different products in following sections:

1. Penicillin Tablet Section.
2. Penicillin Capsule Section.
3. Penicillin Syrup Section.
4. Cephalosporin Tablet Section.
5. Cephalosporin Capsule Section.
6. Cephalosporin Syrup Section.
7. Hormonal Tablet Section.

Decision: **Registration Board after deliberation on the inspection report of FID, decide to issue a show cause notice as why the registrations granted in the following sections not be suspended under section 42 of the Drugs Act 1976, the DRAP Act 2012;**

1. Penicillin Tablet Section.
2. Penicillin Capsule Section.
3. Penicillin Syrup Section.
4. Cephalosporin Tablet Section.
5. Cephalosporin Capsule Section.
6. Cephalosporin Syrup Section.
7. Hormonal Tablet Section.

Case. No.04: Standardization/Correction of Label Claim as Per Reference / Innovator Product.

a. M/s. Care Pharmaceuticals 8-Km Thokar Raiwind Road Lahore

Registration Board in its 249th meeting approved following product of M/s. Care Pharmaceuticals 8-Km Thokar Raiwind Road Lahore. Registration letter was not issued for confirmation of product's approval status in Reference Regulatory Authorities as RRA approved formulation is Fluocinolone acetonide 0.25mg (0.025%w/w) instead of Fluocinolone acetonide 2.5mg (0.25%w/w). Firm has requested

to correct label claim as per RRA. Firm has also submitted fee of Rs.30,000/- vide challan No. 97701652 along with revised Form-5 for correction in strength of product. Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	Sinocare Cream Each gm contains: Fluocinolone acetonide…2.5mg	Sinocare 0.025% Cream Each gm contains: Fluocinolone acetonide…0.25mg (USP Specifications)	**RRA:** MHRA Approved **Me-Too:** Flucinate Cream 0.025% w/w Reg. No. 094808 M/s. Atco

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Sinocare 0.025%w/w Cream
Each gm contains:
Fluocinolone acetonide…0.25mg (0.025% w/w)
(USP Specifications)"

b. M/s. Skims Pharmaceuticals 10-B, Value Addition City Khurrianwala, Faisalabad.

Registration Board in its 283rd meeting approved following product of M/s. Skims Pharmaceuticals 10-B, Value Addition City Khurrianwala, Faisalabad. Registration letter was not issued due to correction in strength of formulation. Firm has also submitted fee of Rs.30,000/- vide challan No. 15038019969 along with revised Form-5 for correction in strength of product . Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	Skinita Sachet 2gm Each Sachet contains **Strontium ranelate….2mg**	Skinita Sachet 2gm Each Sachet contains **Strontium ranelate….2gm** (As per Innovator's Specifications)	**RRA:** MHRA Approved **Me-Too:** Strebon Sachet 2gm Reg. No. 088263 M/s. Barrett Hodgson

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Skinita Sachet 2gm
Each Sachet contains
Strontium ranelate….2gm
(As per Innovator's Specifications)"

c. M/s. Allmed (Pvt) Ltd. Plot No. 590 Sundar Industrial Estate Lahore.

Registration Board in its 257th meeting approved following product of M/s. Allmed (Pvt) Ltd. Plot No. 590 Sundar Industrial Estate Lahore and rregistration letter was not issued. Firm has submitted fee of Rs.30,000/- vide challan No. 623289154671 along with revised Form-5 for correction in strength and pack size of product as MHRA approved strength if 2mcg/ml instead of 1mcg/ml. Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	A-Bone Injection IV 15ml Ampoule/Oral Ampoule Each ml contains **Alfacalcidol BP …. 1mcg** (BP Specification)	A-Bone Injection IV 1ml Ampoule/Oral Ampoule Each ml contains **Alfacalcidol BP …. 2mcg** (BP Specification)	**RRA:** MHRA Approved **Me-Too:** Calfram 2mcg/ml Injection Reg. No. 099691 M/s. Pharmasol

Decision: **Registration Board decided to approve the correction in above product with following details.**

"A-Bone Injection IV (1ml)
Ampoule/Oral Ampoule
Each ml contains
Alfacalcidol BP …. 2mcg

(BP Specification)"

Post Registration-I Section

M/s GlaxoSmithKline Pakistan Limited, Plot No.5, Sector 21, Korangi Industrial Area, Karachi has request for grant of Manufacturer's specification for the product "Chewcal Tablet Registration No. 019881"

1.		**M/s GlaxoSmithKline Pakistan Limited, Plot No.5, Sector 21, Korangi Industrial Area, Karachi.**			
1.	019881	Chewcal Tablet Each tablet contains: Elemental calcium BP……400mg Vitamin D……2.5mcg	Chewcal Tablet Each tablet contains: Elemental calcium BP……400mg Vitamin D……2.5mcg (Manufacturer's Specifications)	15/08/2016 05-09-2023	Fee Rs. 10,000/- Deposit Slip No. 99530146 R&I Dy. No. 21122 Dated: 28/08/2023
Remarks		The firm has submitted the case for change of specifications to Manufacturer's Specification.			
Decisions of 109th PRVC:-		The Chairman Registration Board on recommendation of committee defer request of firm for confirmation of RRA status of product.			
Justification submit by the firm		One of the core material i.e. Cholecalciferol, associated with preparation of Calcium and Cholecalciferol Chewable Tablet referred to BP Monograph, has appearance i.e. White or almost white crystals, however the material Cholecalciferol (Vit D3) being used in GSK formulation for the product chewable tablet has, Dry Vitamin D3 CWS/AM in the form of Beadlets. They contain Vitamin D3 in medium chain triglycerides finely dispersed in corn starch coated matrix of acacia gum, sucrose and dl-α- tocopherol and provide enhanced stability in formulation as compared to free vitamin D3. Furthermore, Vitamin D3 assay cannot be performed using BP monographs due to different nature of Vitamin D3 used in GSK Formulation			
Remarks		The case was again placed in 119th PRVC with justification submitted by firm.			
Decisions of 119th PRVC:-		Chairman Registration Board on recommendation of committee refer the case to Registration Board. The case was placed before 109th Meeting of PRVC. Firm has submitted evidence of MHRA, which is also chewable tablet with different strength. The firm could not provide any evidence of RRA for the applied formulation / strength. As per record the firm is holding registration of plain tablet, with following formulation: ➢ Elemental Calcium BP… 400mg Vitamin D… 2.5mcg While the MHRA reference provide by the firm is "Chewable Tablet" with following formulation: ➢ Calcium Carbonate… 1500mg Cholecalciferol… 400 IU Furthermore, British Pharmacopeia also described Calcium and Cholecalciferol as "Chewable Tablet".			
Remarks:-		The matter is placed before the Registration Board in light of decision of 104th PRVC meeting.			
Decision:-		**Deferred for the submission of following shortcoming:** • **Submit evidence of availability of applied formulation in the approved reference regulatory agencies. OR** • **In case of adopting Manufacturer's specification, firm has to provide the data as mentioned in the "*guidance document regarding application of Drug Product specification*" notified vide letter No.9-2/2022-PEC dated 18th December,2023.**			

Case No.2. Request for Change in Registration Status, MA holder of Invital D 5mg/5mL Injection from M/s Ray Pharma, Karachi to M/s Kaizen Pharmaceutical Pvt. Ltd., Karachi.

M/s. Kaizen Pharmaceutical Pvt Ltd, Karachi, E-127-129, North Western Industrial Zone, Bin Qasim Karachi has requested to change the product registration status of **Invital D 5mg/5mL injection** from M/s Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi to their name. However, the product will continue to be manufactured at Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi through contract manufacturing.

The details of the application is as follows:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML (000755) of Kaizen Pharmaceutical Pvt Ltd, Karachi, E-127-129, North Western Industrial Zone, Bin Qasim Karachi renewed w.e.f 24-09-2022.
ii. Copy of DML of Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi (DML # 000642) renewed w.e.f. 05-09-2018 (renewal applied on 04 Sep 2023).
iii. Copy of DRAP's letter dated 14th Feb 2020 for renewal of DML of M/s Ray Pharma (Pvt) Ltd, Karachi mentioning Liquid Ampoule (General) among formulation sections
iv. NOC from M/s. Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi for transfer of Invital D Inj on the name of M/s. Kaizen Pharmaceutical Pvt Ltd, Karachi, E-127-129, North Western Industrial Zone, Bin Qasim Karachi issued 25-01-2024
v. Relevant undertakings & commitments.

1.	**Name of Product and Composition (as per initial Registration letter)**	**Registration Trail**
	Genvit-D 5mg Injection Each ml Contains: Cholecalciferol……5mg (eq. to 200,000 IU of Vitamin-D) (Manufacturer's Specification) (Reg# 061284)	Initial Registration: **08-04-2010** Change of Brand Name to Invital D: **10-06-2010** Last Renewal Submitted on: **03-02-2020**
	Name, address of Applicant / Marketing Authorization Holder	**M/s Kaizen Pharmaceutical Pvt Ltd, Karachi, E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi **(DML # 000642)**
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm	**For transfer of registration:** The inspection report concluded M/s Ray Pharma Pvt Ltd, Karachi is running at a good level of GMP compliance based on the inspection conducted on 18-01-2024 by FID, Karachi.
	Evidence of approval of manufacturing facility	Applicant has provided a letter of DML renewal of manufacturing site showing Liquid ampoules (General) among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12569 R&I : 23-05-22 Dy. No. 2412 :R&I 26-04-2023
	Details of fee submitted	**For transfer of registration:** PKR 50,000/-: DS No. 0830163 deposited on 24-04-2020 PKR 30,000/- DS No. 7851710960 deposited on 19-01-2024

	The proposed proprietary name / brand name	**Invital D injection (Reg.102826)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Cholecalciferol B.P…… 5mg eq. to 200,000 IU of Vitamin D
	Pharmaceutical form of applied drug	Injection: Pale Yellow colour oily liquid, free from visible particles, packed in 1ml Amber Glass D-type ampoule
	Pharmacotherapeutic Group of (API)	Vitamins
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1x10's 1x5's
	Proposed unit price	-
	The status in reference regulatory authorities	Sapvit – D3 Inj, Fresenius Kabi (Austria)
	For generic drugs (me-too status)	Miura D Injection, Getz Pharma Pvt Ltd,. (Reg# 024254)
	Name and address of API manufacturer.	M/s Dishman Carbogen Amics Ltd, Paiki sub plot no 1 Village ladariyal, taluka sanad, Ahmmedabad, 38220 India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	The firm has summarized information related to DS and finished products. QOS provides information of DS manufacturer. Both DS and finish product comply to in-house specification. Brief information related to analytical procedures, specification, container closure system and stability studies of drug substance and drug product has been provided. Batch Analysis, manufacturing process and critical process parameters were summarized for FP. The analytical method of DS was verified by the FPP manufacturer. Stability data sheets of DS and DP were provided at the accelerated and long-term conditions.
	Module-III Drug Substance:	The Firm has submitted Information for drug substance with related to nomenclature and structure, and provided list of general properties including appearance, solubility, optical rotations, The DS was manufactured at Dishman Carbogen Amics India as crystal form. The manufacturing process was described briefly along with critical process steps and the studies conducted for structural elucidation using various analytical techniques. The potential Impurities were listed and residual solvent were studied in 03 batches of DS, which shows detection within limits.DS manufacturer defined inhouse specifications and CoA of DS lot from DS manufacturer and FP manufacturer was provided. Batch Analysis of 03 batches produced in 2018 was provided. CoA of working standards produced by DS manufacturers was submitted. Container closure system and specification for packaging material was provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of each 58 Kg drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months and the long-term stability data is conducted at 2-89°C for 60 months. The DS was placed in double poly bags and kept in an HDPE drum. The DS remain stable and no significant changes were observed during the stability studies.

		DS manufacturer has also conducted
	Module-III Drug Product:	Firm has submitted data on drug product including its description, composition,, manufacture, manufacturing process, process control, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. The Specifications and control tests are in compliance to manufacture's inhouse method. The manufacturing process of DP and critical parameters were identified with control checks. Manufacturing protocol was also developed. Pharmacopeial grade excipients were used in the formulation and their analytical methods and CoAs were provided. The DP specification were assigned as per inhouse method and accordingly analytical method was verified. Batch analysis of 03 stability batches were provided. Working standard provided by the DS manufacturer were used as reference standard. BMR of stability batches was also submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The Pharmaceutical equivalence study was conducted to compare DP against the Vitamin D3 Good Injection manufactured by Bouchara Recordati (Batch #ATRC14 , Exp 09-2010), which shows comparable results.
	Analytical method validation/verification of product	Firm has claimed in-house specifications for which a report of validation of analytical method for the drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Dishman Carbogen Amics Ltd, Paiki sub plot no 1 Village ladariyal, taluka sanad, Ahmmedabad, 38220 India		
API Lot No.	CWD1D15052		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 6 months Real time: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,36 (Months)		
Batch No.	15l988	14l939	15l989
Batch Size	40 Litres	40 Litres	40 Litres
Manufacturing Date	01-2015	10-2014	01-2015
Date of Initiation	01-2015	01-2015	01-2015
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Control Administration, Gujrat State, India valid till 01-05-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 25Kg of Cholecalciferol dated 10-Feb-2016, .
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The data logger provided for accelerated and real-time stability studies of FPP does not correlate with the study period.

Evaluator Queries:

Section	Deficiencies	Comments/Reply
1.	Submit differential fee as applicable for change in Registration status and Contract Manufacturing of Pharmaceutical drug product.	Challan of differential fees PKR 30,000 Challan # is: 7851710960 deposited on 19-01-24.
2.	Provide complete registration renewal trail of product.	Registration trail was provided however
3.	Latest GMP Inspection report of M/s Ray Pharmaceutical Karachi.	GMP Inspection report of M/s Ray Pharma conducted on Jan-24 was provided.
4.	Valid Drug Manufacturing License of Applicant (M/s Kaizen Pharmaceuticals, Karachi)	Valid Drug Manufacturing License of M/s Kaizen Pharmaceuticals was provided.
5.	Fresh NOC from existing registration holder of Invital-D Injection with date and authorized signatures.	Fresh NOC from existing registration holder of Invital-D Injection i.e., Ray pharma was provided
6.	Submit relevant undertakings with dates and names of signatories.	Submitted
7.	Provide notarized copy of contract manufacturing agreement as per Rule 20-A of the Drug LRA Rules, 1976.	Notarized copy of contract manufacturing agreement as per Rule 20-A of the Drug LRA Rules, 1976 attached
8.	Documents for procurement of DS with approval from DRAP.	Attached.
9.	DS Monograph is available in Pharmacopeia (e.g. BP), Justify the use of in-house specification. Please provide comparison with monograph specifications.	Results of both methods i.e., pharmacopeial and in-house method are same. Our in-house method is also stability indicating method (SIM) as mentioned in section 21. The assay results obtained through both methodologies, along with the accompanying raw data, were provided.
10.	Stability studies of DS are not performed under Zone IV (a) conditions for at least 06 months at real time and accelerated conditions, please provide the same with data logger for entire transportation storage of DS, forced degradation studies of finished product with at least 01-year real time stability studies as per the decision of Registration Board.	Storage condition of Cholecalciferol is 2°C-8°C (refrigerator). As per ICH guideline Q1R2, section 2.1.7.2 long term stability studies for Drug substances intended for storage in a refrigerator shall be done at 2°C-8°C having no humidity requirements. And accelerated studies shall be done at 25°C ± 2°C/60% RH ± 5% RH.
11.	Justification for selection of excipient during pharmaceutical development?	Ethyle oleate is used as solvent for cholecalciferol in the manufacturing of injection during pharmaceutical

		development because (1) Cholecalciferol is much stable in ethyl oleate, (2) the same excipient has been used by the innovator and (3) As per the monograph of Cholecalciferol Injection in BP 2023, ethyl oleate shall be use as solvent for the manufacturing of cholecalciferol injection. Reference of BP-2023 is attached.
12.	Justification for using this much quantity of overages?	In the pharmaceutical development phase, due to the degradative nature of cholecalciferol, overages were initially incorporated to offset potential degradation. However, following a two-year stability assessment, the New Product Development department recommended to production that the overage be eliminated from the product formulation. Consequently, current manufacturing practices involve producing batches without any overage.
13.	It would be more appropriate to perform pharmaceutical equivalence studies against the reference product/innovator product and include all related parameters. Currently, only assay and physical appearance has been compared.	Pharmaceutical equivalence studies against the reference product is attached including physical test, identification test, assay test, sterility test and endotoxin test.
14.	Physical appearance of DP solution is mentioned as white to off white during formulation development, but it has been changed to pale yellow color during stability studies. Please explain.	The physical appearance of the drug product solution is consistently described as a pale-yellow color across all documents, including formulation development and stability studies. There have been no observed differences in the appearance of the solution in both sets of data.
15.	The acceptance range criteria for assay has been enhanced to 90-140% in specification, however, DP is not losing potency to this extent as evident from stability studies, please justify?	During the product development phase, overages were introduced to offset potential degradation of cholecalciferol due to its degradative nature. However, following a comprehensive two-year stability assessment, the New Product Development department recommended to production the removal of overages from the product formulation. Consequently, our current manufacturing practices involve producing batches without any overages.
16.	The master formula shows composition of DS as 6mg/ml but in the assay results it appear as more than 6mg till the 06 months of studies despite of its photolytic tendency.	After 6th month stability studies, there is no degradation observed despite photolytic tendency of the analyte. This is due to the stable formulation using ethyl oleate as solvent. Secondly the drug product solution is kept in amber glass ampoules and then packed in unit opaque unit carton to protect it from light. Slight increase in the assay results might be due to improper sample preparation during analysis.
17.	Valid GMP certificate of DS manufacturer issued by relevant regulatory authority.	Valid GMP certificate of DS manufacturer issued by relevant regulatory authority provided.
18.	Provide analytical method validation studies of DS performed by M/s Ray Pharmaceutical, Karachi.	Analytical method validation provided
19.	CoA of relevant batches of DS.	COA Provided
20.	Protocols for carrying out stability studies for trial batches.	Protocols for carrying out stability studies for trial batches provide
21.	Please justify your analytical method for drug product is stability indicating method (SIM).	To establish the method's stability indicating nature, a specificity test was conducted on the finished product

		through force degradation methodology. The report encompasses force degradation studies involving acid hydrolysis, basic hydrolysis, thermal degradation, oxidation reaction degradation, and photolytic degradation. The results demonstrate that the impurity formed due to the degradation of cholecalciferol is clearly distinguished from the analyte in terms of retention time. This separation confirms the method's capability to detect and quantify degradation products, validating it as a stability-indicating method (SIM).
22.	Why impurity testing is not performed during stability studies.	As our in-house testing method is SIM method, if any impurity formed during stability studies it will be observed in the chromatogram. Therefore, any separate impurity test was not performed.
23.	Why DS identification, optical rotation, sterility and microbial tests were not included in the stability studies.	Identification is verified by HPLC method for assay. Optical rotation property is not susceptible to change during storage condition, therefore not included in the stability studies. Sterility test is not performed on DS as the material is not sterile.
24.	Data loggers for temperature and humidity monitoring during stability studies.	Data from Data loggers for temperature and humidity monitoring during stability studies were provided.

Evaluator Remarks:

- The data logger attached in the response covers the years 2020 to 2022. However, the stability data of the FPP indicates that the stability study was conducted in 2015. Additionally, the chromatogram and CoAs of the stability testing have not been provided.

Decision: Registration Board acceded to the request of firm for change of market authorization of product Invital D injection (Reg.102826) from M/s Ray Pharma, Karachi to M/s Kaizen Pharmaceutical Pvt. Ltd., Karachi. However, the product will continue to be manufactured at Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi through contract manufacturing.

Post Registration-II Section

Case No.01: Cases of Change of Manufacturer from Self Manufacturing to Contract Manufacturer

1.	Name, address of Applicant / Marketing Authorization Holder	**M/s. Vision Pharmaceuticals (Pvt.) Ltd. 22-23, Industrial Triangle Kahuta Road Islamabad.**
	Existing manufacturer	M/s. Vision Pharmaceuticals (Pvt.) Ltd. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Name, address of Manufacturing site.	M/s. Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17641 (dated: 13-07-2023)

	Details of fee submitted	PKR75,000/-: dated: 12-07-2023 (Invoice # 060541871)
	The proposed proprietary name / brand name	**Doston 8mg Injection** (Reg.No.081892) Dated: 26-10-2016 Renewed till 25-10-2026
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains:- Ondansetron hydrochloride equivalent to Ondansetron……8mg
	Pharmaceutical form of applied drug	Liquid injection.
	Pharmacotherapeutic Group of (API)	Anti-emetic.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	4ml x 5's
	Proposed unit price	As per S RO
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too status)	Zofran 8mg Injection of M/s Novartis Pharma (Pakistan) Limited
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s Global Pharmaceuticals (Pvt.) Ltd. (DML. No. 000417) Copy of GMP certificate No. 3-16/2018-Addl. Dir. (QA&LT-I)-1 dated 04-01-2022 valid till 02.01.2024.
	Evidence of section approval.	Liquid Injection (General) section (as per GMP Certificate).
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat-394-230 Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, Total Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time**: 30˚C ± 2˚C / 65% ± 5%RH for 60 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**:ON130001, ON130002, ON130003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Test product:**Ondoglob 8mg/4ml Injection Batch No. ST22M020 byM/s Global Pharmaceuticals.

		Reference Product: Zofran 8mg/4ml Inejction (Batch No. HM5Y Mfg: 05.2021, Exp 04.2024) manufactured by M/s GSK Italy Pharmaceutical Equivalence is established against the comparator Zofran 8mg/4ml Inejction (Batch No. HM5Y Mfg: 05.2021, Exp 04.2024) manufactured by M/s GSK Italy by performing quality tests (Physical attributes, Identification, Assay and pH test). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method validation studies are submitted including specificity, linearity and range, accuracy (recovery), repeatability, robustness and precision.

STABILITY STUDY DATA		
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat-394-230 Gujrat, India.	
API Lot No.	22ON000017 Mfg 01.03.2022 Exp 28.02.2027	
Description of Pack (Container closure system)	Clear glass Ampoule 4ml.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST22M020	ST22M020
Batch Size	2000 Ampoules	2000 Ampoules
Manufacturing Date	12-2022	12-2022
Date of Initiation	08.12.2022	08.12.2022
No. of Batches	02 (Commercial batches)	

Administrative Portion		
19.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
20.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of manufacturing licence # G/25/1723 Valid till 23-01-2026 issued by Food & Drug Control Administration Ghandinagar 382 010, in the name of M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat-394-230 Gujrat, India is submitted.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance certificate issued by DRAP Islamabad is submitted. As per clearance certificate material was cleared in name of M/s Vision pharmaceuticals. The firm has submitted a letter addressed to M/s Vision Pharmaceuticals for request of loan of API Ondansetron 100gm. The request is dated 06.12.2022.
22.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
23.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.

24.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks oF Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	**3.2.S.5**	CoA of working standard for analysis of drug substance by Global Pharmaceuticals (Pvt) Ltd. shall be submitted.	Submitted.
2.	**3.2.P.3.3**	Justification shall be submitted for not performing terminal sterilization of applied product.	Firm has submitted that they are performing terminal sterilization of the product.
3.	**3.2.P.8.3**	Justification shall be submitted for not establishing system suitability as per USP monograph during drug product analysis.	Firm has submitted that system suitabilityhas been performed as per US monograph of Ondansetron injection.
4.	**2.3 .R.1.1**	Justify the dispensed weight of Ondansetron HCl for each batch.	Justification along with calculation has been submitted.

- The said product is already registered on the name of M/s Vision Pharmaceuticals (Pvt) Ltd. and they submitted the justification of manufacturing from M/s Global Pharmaceuticals (Pvt)Ltd. that their section is under renovation.
- As per attached clearance certificate the Drug substance was imported by M/s Vision pharmaceuticals (Pvt) Ltd. instead of M/s Global Pharmaceuticals (Pvt) Ltd. The contract acceptor has submitted that drug substance was taken as loan from M/s Vision pharmaceuticals (Pvt) Ltd. but such intimation is not submitted to DRAP.
- Capacity assessment of the firm M/s Global Pharmaceuticals Pvt. Ltd., (DML#000417) was conducted on 21-10-2022 for the following sections: -

Sr. #	Section	Capacity Available as per Report date 21-10-2022
i.	**Dry powder Injection (cephalosporin)**	**27.66%**
ii.	**Dry powder Injection (Penicillin)**	**78.88%**
iii.	**Dry powder Injection (Carbapenem)**	**83.28%**
iv.	**Liquid Injection ampoule (general)**	**42.35%**

The case was considered in 111th meeting of PRVC wherein following was decided:
"The Chairman Registration Board on recommendation of Committee advised to place the case before Registration Board after submission of justification for toll manufacturing of Doston 8mg/4ml Injection, as the firm M/s Vision Pharma has already approved Liquid Injection (General) section."
Now, the firm has submitted the following:
"This change has been made because of maintenance work at manufacturing facility. The decision has been taken to avoid the shortage of product in market which may cause patient inconvenience".

Decision:

Registration Board acceded to the request of the firm for contract manufacturing of their registered product Doston 8mg Injection (Reg. No. 081892) from M/s. Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad under Rule 20A (1) (d) of the Drugs (Licensing, Registration & Advertising) Rules, 1976 for a period of thirty (30) months only subject to capacity assessment of M/s. Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad.

Case No.02: Change of Brand Name Due to Similarity/Resemblance.

M/s. Abbott Laboratories Pakistan Limited, Karachi has informed that our product Duphaston Registration No.006654 resemblance with M/s. Lahore Chemical & Pharmaceutical Works (Pvt) Ltd. Lahore vide their product Efaston 10mg Tablets Registration No.064835. Accordingly, letter issued to M/s. Lahore Chemical & Pharmaceutical Works (Pvt) Ltd. Lahore to change of brand name. In response the firm has informed that;

It is very surprising that our product Efaston 10mg resemble with Duphaston. We investigate at our end and found following points for clarification.

- No resemblance pronunciation.
- No resemblance found in unit cartoon design/blister.
- No color resemblance.

Keeping in view the above in spite of marketing jealousy it has nothing to do with each other. But only the wish of Abbot Laboratories Pakistan Limited to address us for seen loss of marketing share.

The case was discussed in 114th meeting of Post Registration Variation Committee discussed the case and the Chairman Registration Board on the recommendation of the committee decided to place the case in forthcoming meeting of Registration Board.

Decision:

Registration Board deliberated that both brand names are not similar, hence, did no accede to the request of M/s Abbot Laboratories Pakistan Limited, Karachi.

Case No.03: Change of Brand Name Due to Similarity/Resemblance.

M/s. Neutro Pharma (Pvt) Ltd., Lahore had informed that their product Neupred Syrup, Registration No.044615 resemble with Neoprad 25mg & 50mg Tablet Registration No.060692 & 060693 of M/s. Mcolson Research Lab. (Pvt) Ltd., Sheikhupura. Accordingly, letter was issued to M/s. Mcolson Research Lab. (Pvt) Ltd., Sheikhupura to change the brand names. In response the firm has informed that;

- We got registration of Neoprad 25mg and 50mg Tablets via Registration No. 060692 & 060693 on 4th December 2009, and immediately started its commercial production. Renewal of registration for Neaprad has always been filed within due course of time. (Letter attached for your reference).
- As of today, Neoprad brand is being prescribed by the leading gastroenterologists and physicians across Pakistan and around 1 million patients per annum are getting benefits from this product.
- Faith of the healthcare professionals and patient's satisfaction has made Neoprad 3rd largest selling Levosulpiride brand in Pakistan.
- We have also got the trademark registration from Intellectual Property Organization of Pakistan via file number 324897 (Copy of the letter is attached).

The firm has requested to advise M/s Neutro Pharma Pvt. Ltd. to change their brand name.

The case was discussed in 115th meeting of Post Registration Variation Committee discussed the case and the Chairman Registration Board on recommendation of Committee decided to refer the case to Registration Board.

Now M/s Neutro Pharma (Pvt.) Ltd., Lahore vide letter dated 03-06-2024 submitted the following:

"With reference to the agenda for the 336th meeting of the Registration Board to be held on June 4-6, 2024, in which Post Registration II - Section Case No. 2, Page No. 2873 discussed our brand name resemblance case, we, M/s Neutro Pharma, would like to discuss a few points for your understanding:

1. Our brand name is Neupred, and the opposing brand from Mcolson Pharma is NeoPrad. According to the DRAP and Trademark rules regarding look-alike and sound-alike names, both names are distinctly different in pronunciation.
2. The first three letters and the last three letters of each brand name are not identical.
3. Both products hold a significant market share.
4. Both products serve different therapeutic markets.
5. We recommend that both products should continue with their current names, provided it is acceptable to your competent authority.
6. We have no objection to the continuation of M/s Mcolson Pharma's brand name "NeoPrad" as they are operating in a different therapeutic market.
7. If the competent authority decides that a name change is necessary, we, M/s Neutro Pharma, hereby declare our willingness to change our brand name from "Neupred" to "Neu-Pred" for the ease of the community."

Decision:

Registration Bard decided to ask M/s Neutro Pharma (Pvt.) Ltd., Lahore to change its brand name as per its willingness to change its brand name vide their letter dated 03-06-2024.

Case No. 04: Change of specifications applied by M/s Bayer Pvt. Ltd., Lahore deferred in 121st PRVC.

Sr. No.	Reg. No.	Brand Name & Composition	Proposed Speciications	Reg. & Renewal date	Fee status
1.	017864	**Progynova Tablet** Each Sugar-coated tablet Contains: - Estradiol valerate…….2mg	**Progynova tablet** Each Sugar-coated tablet Contains: - Estradiol valerate…….2mg (Bayer/Innovator Specification)	Reg.Date: - 27-09-1995 Renewal Date: - 26-09-2020 Submission Date: - 08-06-2020	Fee Rs 5,000 deposited date: 15-04-2021
2.	018207	**Climen Tablets** Calendar pack containing 11 tablets of 2mg estradiol valerate plus 10 tablets of 2mg estradiol valerate and1mg cyproterone acetate	**Climen Tablets** Calendar pack containing 11 tablets of 2mg estradiol valerate plus 10 tablets of 2mg estradiol valerate and 1mg cyproterone acetate (Bayer / Innovator's Specification)	Reg.Date: - 27-09-1995 Renewal Date: -26-09-2020 Submission Date: -08-06-2020	Fee Rs 5,000 deposited date: 15-04-2021
3.	024076	**Meliane Tablet** Each tablet Contains: - Gestodene…..0.075mg Ethinylestradiol..0.02mg	**Meliane Tablet** Each tablet Contains: - Gestodene……..0.075mg Ethinylestradiol….0.02mg (Bayer/Innovator's Specification)	Reg.Date: - 15-03-2002 Renewal Date: -14-03-2017 Submission Date: -23-01-2017	Fee Rs 5,000 deposited date: 15-04-2021
Decision of 85th PRVC:	*The Committee evaluated the case and approved the request of firm for grant of innovator's specifications for above mentioned products.*				
Remarks:	The cases were approved in 85th PRVC, however during issuance of approval letter it was observed that dissolution test limits of BP general monograph are stringent than of the firm's. Hence, letter was not issued and firm was asked for clarification. Now the firm has revised limits as per BP monograph.				
Decision of 121st PRVC	*The Chairman Registration Board on recommendation of Committee referred the cases to Registration Board.*				

Decision:

Registration Board acceded to the request of the firm for change in finished product specifications of above products to "Bayer/ Innovator's Specifications".

Case No. 5: M/s. OBS Pharma (Pvt.) Limited, 108-Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore.

M/s. OBS Pharma (Pvt.) Limited, Lahore has requested for additional source of API for their registered drug (s). The details are as under:-

Sr.#	Reg. No.	Name of drug with composition& Reg. No.	Date of Initial Reg. & Renewal	Existing Source	Proposed Additional Source
I	II	III	IV	V	VI
1.	107221	Ciproxin 250mg Tablet	15-01-2023	M/s. Bayer AG, Wuppertal, Bayer AG, Werksteil Elberfeld Friedrich-Ebert-Straβe 217-333 42117, Wuppertal, Germany.	M/s. Zhejiang Guobang Pharmaceutical Co., Ltd., No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological

					Development Zone, Zhejiang, P.R. China.

The firm has submitted the following documents:

Sr.#	Required documents as per approved SOPs	Submission
1.	Application with required fee as per relevant SRO.	Rs. 75,000/- deposited (77457718823) datred 16-01-2024
2.	Complete CTD section S1-S7 as per DRAP guidance document on CTD (Form5F)	Provided
3.	Comparative tabulated format of the approved and proposed drug substance manufacture information (where applicable).	Provided
4.	Certificate of analysis and/or batch analysis data (in a comparative tabulated format) for at least two pilot batches of the drug substance from the approved and proposed manufacturing sites	Not Provided
5.	A letter of commitment from marketing authorization/ registration holder to conduct long term and accelerated stability studies for the drug product manufactured with the drug substance from the proposed manufacturing site, and report if any results fall outside shelf-life specifications (with proposed action) or when requested	Provided

Remarks:

Chairman Registration Board is not authorized for such cases by Registration Board.

Decision of 118th PRVC:

The Chairman Registration Board on the recommendation of the Committee advised to place the case before Registration Board after submission of following by the firm:

i. Differential fee of Rs. 225,000.
ii. Copy of Registration letter.
iii. Certificate of analysis and/or batch analysis data (in a comparative tabulated format) for at least two pilot batches of the drug substance from the approved and proposed manufacturing sites.
iv. Evidence of No objection for change in source of API from the MA Holder abroad & pre-qualification of new source by the MA Holder abroad.

Now, the firm has submitted the following documents:

i. Differential fee of Rs. 225000/- vide Challan No. 61278385
ii. Certificate of analysis for three batches of the drug substance from the approved and proposed API manufacturing sites.
iii. Copy of Authorization letter from M/s Bayer Pharma AG, Germany authorizing OBS Pharma to oversee the addition and change of API and excipient sources.
iv. Certificate of suitability (CEP) for Ciprofloxacin Hydrochloride issued in name of M/s Zhejiang Guobang Pharmaceutical Co., Ltd. Shangyu CN.

The firm has also submitted the application for above mentioned additional source of API for their registered product Ciproxin 500mg Tablet (Reg. No. 107222) and paid fee of Rs. 300000 vide challan no. 1144535068 & 30401165552.

Decision:

Registration Board acceded to the request of the firm for additional source of API from M/s. Zhejiang Guobang Pharmaceutical Co., Ltd., No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P.R. China for their already registered drugs Ciproxin 250mg Tablet (Reg. No. 107221) & Ciproxin 500mg Tablet (Reg. No. 107222).

PRVC CASES EVALUATED BY MR. SALATEEN WASEEM PHILLIP

Case No. 06: Change of Registration Holder (MA holder) along with Change in Manufacturing Site

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**

	Change of Registration Holder (MA Holder)	
	From M/s. Lucky Core Industries (formerly M/s ICI Pakistan Limited) **(DML # 000363)** 32-2A, Phase III, Industrial Estate, Hattar.	**To** **M/s The Searle Company Limited (DML # 000016)** **F-319, S.I.T.E. Karachi**
	Request of Contract Manufacturing	
	Contract Giver (Applicant) **M/s The Searle Company Limited (DML # 000016)** **F-319, S.I.T.E. Karachi**	**Contract Acceptor** M/s CSH Pharmaceuticals (Pvt.) Ltd. **(DML # 000737)** 32-km. Ferozepur Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 26191 dated 30-10-2023
	Details of fee submitted	PKR 75,000/-: dated: 23-10-2023 (Invoice # 11781477693)
	The proposed proprietary name / brand name	**Capsule Zeemox 250 mg *(Reg. # 015964)***
		Initial Registration: 20th September 1994
		Transfer of Registration: *(From Cirin to ICI Pakistan)* 03rd March 2020
		Transfer of Registration: *(From ICI to Lucky Core Industries)* 01st March 2023
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Amoxicillin Trihydrate Equivalent to Amoxicillin……...…..……..…250 mg
	Pharmaceutical form of applied drug	Oral Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	20's & 100's
	Proposed unit price	20's → PKR 150 100's → PKR 650
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Amoxil ®** approved for M/s GSK
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **29th November 2024**
	Name and address of API manufacturer.	**Amoxicillin Trihydrate Compacted** M/s Pharmagen Limited.

		Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. **GMP valid till 17-11-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30°C ± 2°C / 65% ± 5% RH for 48 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** AMOXIL® **Manufacturer: GSK** **Testing Parameters:** BP Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Trihydrate Compacted** M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore.		
API Lot No.	000120/439/2015		
Description of Pack (Container closure system)	ALU-PVC Blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**OX/CAP250/001**	**OX/CAP250/002**	**OX/CAP250/001**
Batch Size	16500 capsules	16500 capsules	16500 capsules

Manufacturing Date	26-12-2012	26-12-2012	13-01-2013
Date of Initiation	12-2012	12-2012	01-2013
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amoxicillin Trihydrate** **Invoice #** 2430 **Dated:** 04-10-2012 **Quantity:** 1000 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).
- Inspection of contract acceptor (CSH) for manufacturing/testing capacity assessment needs to be conducted because firm has not been inspected for such purpose for last three years.

Section	Observations	Status
1.1	• Affidavit on stamp paper (Showing name, designation, CNIC number of Contract Giver) **stating installed capacity of the contract acceptor for contract manufacturing.**	Submitted
	• Please repeat the format of Contract and submit legalized copy of contract between contract giver and contract acceptor on stamp paper presenting the capacities of the contract acceptor for the manufacturing sections for whom the products have been applied.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration holder (MA holder) and change of manufacturing site as under

Capsule Zeemox 250 mg *(Reg. # 015964)*

(Existing)	**(Proposed)**
Drug Product Registration Holder along with manufacturing site M/s. Lucky Core Industries (DML # 000363) (*formerly M/s ICI Pakistan Limited*) 32-2A, Phase III, Industrial Estate, Hattar.	**Drug Product Registration Holder** M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi **Drug Product Manufacturing Site (Contract Basis)** M/s CSH Pharmaceuticals (Pvt.) Ltd. **(DML # 000737)** 32-km. Ferozepur Road Lahore.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**
	Change of Registration Holder (MA Holder)	
	From M/s. Lucky Core Industries	**To** **M/s The Searle Company Limited (DML # 000016)**

	(*formerly M/s ICI Pakistan Limited*) **(DML # 000363)** 32-2A, Phase III, Industrial Estate, Hattar.	**F-319, S.I.T.E. Karachi**
	Request of Contract Manufacturing	
	Contract Giver (Applicant) **M/s The Searle Company Limited (DML # 000016)** **F-319, S.I.T.E. Karachi**	**Contract Acceptor** M/s CSH Pharmaceuticals (Pvt.) Ltd. **(DML # 000737)** 32-km. Ferozepur Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 26192 dated 30-10-2023
	Details of fee submitted	PKR 75,000/-: dated: 23-10-2023 (Invoice # 43370053996)
	The proposed proprietary name / brand name	**Capsule Zeemox 500 mg *(Reg. # 015965)***
		Initial Registration: 20th September 1994
		Transfer of Registration: *(From Cirin to ICI Pakistan)* 03rd March 2020
		Transfer of Registration: *(From ICI to Lucky Core Industries)* 01st March 2023
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Amoxicillin Trihydrate Equivalent to Amoxicillin……...…..……..…500 mg
	Pharmaceutical form of applied drug	Oral Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	20's, 50's & 100's
	Proposed unit price	20's → PKR 400 50's → PKR 650 100's → PKR 920
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Amoxil** ® approved for M/s GSK
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **29th November 2024**
	Name and address of API manufacturer.	**Amoxicillin Trihydrate Compacted** M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore. **GMP valid till 17-11-2024**

	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** AMOXIL® **Manufacturer:** GSK **Testing Parameters:** BP Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Trihydrate Compacted** M/s Pharmagen Limited. Kot Nabi Bukshwala, 34-km Ferozepur Road, Lahore.		
API Lot No.	000120/439/2015		
Description of Pack (Container closure system)	ALU-PVC Blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**13OB03**	**13OB02**	**13OB01**
Batch Size	1,65,016 capsules	1,65,016 capsules	1,65,016 capsules
Manufacturing Date	29-11-2013	27-11-2013	12-09-2013
Date of Initiation	11-2013	11-2013	11-2013

No. of Batches	03	
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import)	**Amoxicillin Trihydrate** **Invoice #** 2430 **Dated:** 04-10-2012 **Quantity:** 1000 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).
- The capacity Assessment inspection of the proposed manufacturing site (CSH) not yet conducted.

Section	Observations	Status
1.1	• Affidavit on stamp paper (Showing name, designation, CNIC number of Contract Giver) **stating installed capacity of the contract acceptor for contract manufacturing.**	Submitted
	• Please repeat the format of Contract and submit legalized copy of contract between contract giver and contract acceptor on stamp paper presenting the capacities of the contract acceptor for the manufacturing sections for whom the products have been applied.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) and change of manufacturing site as under

Capsule Zeemox 500 mg *(Reg. # 015965)*

(Existing)	**(Proposed)**
Drug Product Registration Holder along with manufacturing site M/s. Lucky Core Industries (DML # 000363) (*formerly M/s ICI Pakistan Limited*) 32-2A, Phase III, Industrial Estate, Hattar.	**Drug Product Registration Holder** M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi **Drug Product Manufacturing Site (Contract Basis)** M/s CSH Pharmaceuticals (Pvt.) Ltd. **(DML # 000737)** 32-km. Ferozepur Road Lahore.

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**
	Change of Registration Holder (MA Holder)	
	From M/s. Lucky Core Industries (*formerly M/s ICI Pakistan Limited*) **(DML # 000363)** 32-2A, Phase III, Industrial Estate, Hattar.	**To** **M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**

	Request of Contract Manufacturing	
	Contract Giver (Applicant) **M/s The Searle Company Limited (DML # 000016)** **F-319, S.I.T.E. Karachi**	**Contract Acceptor** **M/s Stallion Pharmaceuticals (Pvt) Ltd. (DML # 000783)** **Plot No. 581 Sunder Industrial Estate Lahore.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 2623 dated 12-02-2024
	Details of fee submitted	PKR 75,000/-: dated: 25-01-2024 (Invoice # 919713027)
	The proposed proprietary name / brand name	**Fortecin Powder for injection 600 mg *(Reg. # 015979)***
		Initial Registration: 20th September 1994
		Transfer of Registration: *(From Cirin to ICI Pakistan)* 03rd March 2020
		Transfer of Registration: *(From ICI to Lucky Core Industries)* 01st March 2023
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for injection)* Amoxicillin Sodium Equivalent to Amoxicillin……..…….……500 mg Potassium Clavulanate equivalent to Clavulanic Acid …… 100 mg
	Pharmaceutical form of applied drug	Sterile powder for reconstitution with 10ml of WFI.
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per registration letter
	Proposed unit price	As per registration letter
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Calamox Injection** approved for M/s Bosch
	Evidence of approval of manufacturing facility	Vials of Sterile Powder (Penicillin) Section, Approval by Central Licensing Board in its 233rd meeting held on 30th & 31st December 2013.
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **19-09-2024**
	Name and address of API manufacturer.	**Amoxicillin Sodium: Clavulanate Potassium (5:1)** M/s Shandong New Time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian, Shandong, China. **GMP valid till 31-12-2023**

	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 5°C ± 3°C for 24 months **Accelerated:** 25°C ± 2°C / 60% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Calamox Injection **Manufacturer:** Bosch Pakistan **Testing Parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA		
Manufacturer of API	**Amoxicillin Sodium: Clavulanate Potassium (5:1)** M/s Shandong New Time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian, Shandong, China.	
API Lot No.	403180017	
Description of Pack (Container closure system)	USP Type I colorless glass vials	
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 24 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)	
Batch No.	**L9001**	**L9002**
Batch Size	14490 vials	14490 vials
Manufacturing Date	04-2019	07-2019
Date of Initiation	08-05-2019	06-07-2019
No. of Batches	03	
Administrative Portion		

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import)	**Dated:** 18-02-2019 **Quantity:** 150 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.1	• Affidavit on stamp paper (Showing name, designation, CNIC number of Contract Giver) **stating installed capacity of the contract acceptor for contract manufacturing.**	Submitted
	• Please repeat the format of Contract and submit legalized copy of contract between contract giver and contract acceptor on stamp paper presenting the capacities of the contract acceptor for the manufacturing sections for whom the products have been applied.	Submitted
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.8	• Please submit data regarding in-use stability of vial after reconstitution.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) and change of manufacturing site as under

Fortecin Powder for injection 600 mg *(Reg. # 015979)*

(Existing)	**(Proposed)**
Drug Product Registration Holder along with manufacturing site M/s. Lucky Core Industries (DML # 000363) (*formerly M/s ICI Pakistan Limited*) 32-2A, Phase III, Industrial Estate, Hattar.	**Drug Product Registration Holder** M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi **Drug Product Manufacturing Site (Contract Basis)** M/s Stallion Pharmaceuticals (Pvt) Ltd. (DML # 000783) Plot No. 581 Sunder Industrial Estate Lahore.

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**
	Change of Registration Holder (MA Holder)	
	From M/s. Lucky Core Industries (*formerly M/s ICI Pakistan Limited*) **(DML # 000363)** 32-2A, Phase III, Industrial Estate, Hattar.	**To** **M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi**
	Request of Contract Manufacturing	

	Contract Giver (Applicant) **M/s The Searle Company Limited (DML # 000016)** **F-319, S.I.T.E. Karachi**	**Contract Acceptor** **M/s Stallion Pharmaceuticals (Pvt) Ltd. (DML # 000783)** **Plot No. 581 Sunder Industrial Estate Lahore.**
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) **☒ Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale **☒ Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 2624 dated 12-02-2024
	Details of fee submitted	PKR 75,000/-: dated: 25-01-2024 (Invoice # 3561856261)
	The proposed proprietary name / brand name	**Fortecin Powder for injection 1.2G *(Reg. # 015980)***
		Initial Registration: 20th September 1994
		Transfer of Registration: *(From Cirin to ICI Pakistan)* 03rd March 2020
		Transfer of Registration: *(From ICI to Lucky Core Industries)* 01st March 2023
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for injection)* Amoxicillin Sodium Equivalent to Amoxicillin……..……..……1000 mg Potassium Clavulanate equivalent to Clavulanic Acid …… 200 mg
	Pharmaceutical form of applied drug	Sterile powder for reconstitution with 10ml of WFI.
	Pharmacotherapeutic Group of (API)	Beta Lactam Inhibitor (Penicillin)
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per registration letter
	Proposed unit price	As per registration letter
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Calamox Injection** approved for M/s Bosch
	Evidence of approval of manufacturing facility	Vials of Sterile Powder (Penicillin) Section, Approval by Central Licensing Board in its 233rd meeting held on 30th & 31st December 2013.
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **19-09-2024**
	Name and address of API manufacturer.	**Amoxicillin Sodium: Clavulanate Potassium (5:1)** M/s Shandong New Time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian, Shandong, China. **GMP valid till 31-12-2023**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure,

		general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 5°C ± 3°C for 24 months **Accelerated:** 25°C ± 2°C / 60% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Calamox Injection **Manufacturer:** Bosch Pakistan **Testing Parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Sodium: Clavulanate Potassium (5:1)** M/s Shandong New Time Pharmaceutical Co. Ltd. No. 01, North Outer Ring Road, Feixian, Shandong, China.	
API Lot No.	ARM1912171	
Description of Pack (Container closure system)	USP Type I, 20ml colorless glass vials with stopper and aluminum seal. Packed in printed unit carton.	
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 24 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)	
Batch No.	**M9005**	**M9007**
Batch Size	28570 vials	28980 vials
Manufacturing Date	11-2019	12-2019
Date of Initiation	19-11-2019	20-01-2020
No. of Batches	03	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import)	**Dated:** 18-11-2019 **Quantity:** 100 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.1	• Affidavit on stamp paper (Showing name, designation, CNIC number of Contract Giver) **stating installed capacity of the contract acceptor for contract manufacturing.**	Submitted
	• Please repeat the format of Contract and submit legalized copy of contract between contract giver and contract acceptor on stamp paper presenting the capacities of the contract acceptor for the manufacturing sections for whom the products have been applied.	Submitted
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.8	• Please submit data regarding in-use stability of vial after reconstitution.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) and change of manufacturing site as under

Fortecin Powder for injection 1.2G *(Reg. # 015980)*

(Existing)	**(Proposed)**
Drug Product Registration Holder along with manufacturing site M/s. Lucky Core Industries (DML # 000363) (*formerly M/s ICI Pakistan Limited*) 32-2A, Phase III, Industrial Estate, Hattar.	**Drug Product Registration Holder** M/s The Searle Company Limited (DML # 000016) F-319, S.I.T.E. Karachi **Drug Product Manufacturing Site (Contract Basis)** M/s Stallion Pharmaceuticals (Pvt) Ltd. (DML # 000783) Plot No. 581 Sunder Industrial Estate Lahore.

Case No. 07: <u>Cases of Change of Manufacturer from Self Manufacturing to Contract Manufacturer along with change of container Closure system (Primary packing)</u>

The firm M/s Martin Dow Marker Ltd. Quetta has submitted request for change of manufacturing site of their product Advit D Injection 200,000IU from own site to M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan along with request to change container closure system from glass ampoule to LDPE ampoule manufactured by BFS technology. The evaluation of submitted dossier is given below;

5.	**From self-manufacturing to contract manufacturing Along with Change in Primary Packaging Material**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**
	Existing Manufacturer	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta. (Self-manufacturing in glass ampoule)
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33666 dated 22-11-2022
	Details of fee submitted	PKR 75,000/- Dated 10-11-2022 Slip #703651794775
	The proposed proprietary name / brand name	**Advit D Injection 200,000IU** *(Reg. No. 93025)* dated: 31-12-2018 Renewed till 30-12-2028
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml LDPE Ampoule contains: Cholecalciferol…….. 5mg (200,000 IU)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-08-2016 specifying Plastic Ampoules (BFS Technology) section.
	GMP status of the firm	Certificate No:58/2022-DRAP (Q)/K issued on 4th April 2022 Plastic Ampoules (General), Cream/Ointment/Lotion/Gel (General), Capsule DPI (Steroidal), Capsule (General), Eye/Ear & Nasal Drops (General), Injectable Ampoule BF (Steroid)
	Pharmacotherapeutic Group of (API)	Vitamin D Analog
	Pharmaceutical form of applied drug	Pale Yellow oily liquid
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	RRA: France Product Name: Vitamin D3 B.O.N
	For generic drugs (me-too status)	Name: Indrop-D Manufacturer: LABORATORIES BOUCHARA RECORDATI Importer: Neutro Pharma Pvt. Ltd Composition: Each ml contains: Cholecalciferol…….. 5mg (200,000 IU) Pack size: 1Ampoule x1ml
	Name and address of API manufacturer.	**Cholecalciferol:** FERMENTIA BIOTECH LIMITED Z-109 B & C, SEZ II, Dahej Taluka – Vagara, Dist: Bharuch-392130 Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

		and drug product is submitted.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Stability study conditions:** Real time: 5°C ± 3°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months **Batches:** Real Time: CLC0416005, CLC0416006, CLC0416007 Accelerated Time: CLC0416005, CLC0416006, CLC0416007
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against product Indrop-D (HP998) manufactured by LABORATORIES BOUCHARA RECORDATI France. CDP: **Not Applicable**.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Cholecalciferol:** FERMENTIA BIOTECH LIMITED Z-109 B & C, SEZ II, Dahej Taluka – Vagara, Dist: Bharuch-392130 Gujarat, India		
API Lot No.	**Cholecalciferol:** Invoice No: TM20190403A, Batch No**:** CLC0419019		
Description of Pack (Container closure system)	LDPE Ampoule		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 ,12 & 24 (Months)		
Batch No.	B#20A003	B#20A004	B#20C009
Batch Size	100 Litres	100 Litres	100 Litres
Manufacturing Date	01-2020	01-2020	03-2020
Date of Initiation	01-2022	01-2022	03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Cholecalciferol:** FERMENTIA BIOTECH LIMITED Z-109 B & C, SEZ II, Dahej Taluka – Vagara, Dist: Bharuch-392130 Gujarat, India Validity: 25-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 18-11-2019. The invoice is cleared by AD (I&E) DRAP
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing along with chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Query	Response
1	As per filling order (manufacturing order, of batch manufacturing record for commercial batches, both LDPE and HDPE are being dispensed. However, the container closure system described for the applied product is that of LDPE ampoule.	Firm has submitted that the container closure system is PE ampule and it was typographical error and written as HDPE instead of LDPE.
2	As per BP/Eu. Ph monograph for API Cholecalciferol, the storage conditions are given as "Under nitrogen, in an airtight container, protected from light, at a Temperature of 2 degree Celsius to 8 degrees Celsius. Provide evidence of availability of required storage facilities of Cholecalciferol.	Firm has submitted the evidence of storage facility of 2-8 ^{o}C and its log however, evidence of 'under Nitrogen' condition is not provided.
3	Provide evidence that the finished drug specification complies innovator specifications.	Firm has submitted that they have developed in-house specification from innovator's specifications, therefore, both are same and they changed product specifications from in-house specifications to innovator's specification and CoA also provided.
4	As per stability summary data sheet submitted for commercial batch No. 20A004, the date of initiation of stability studies given as 13-01-2020, while date of initial testing mentioned as 18-01-2020.	Firm has submitted that it was typographical error which they have corrected it and revised data sheet provided.
5	As per COA of finished product (Vydee injections) of contract acceptor, the product complies in-house specification. While for the applied product of contract giver, the innovator specifications mentioned.	Firm has submitted that they have developed in-house specification from innovator's specifications, therefore, both are same and they changed product specifications from in-house specifications to innovator's specification and CoA also provided.

6	As per in-process ampoule filling record, the fill volume given as 1.2ml, while strength/ concentration of applied product is Cholecalciferol… 5mg/ml. Justify excess filling volume since a 20% extra API (Cholecalciferol) as overage had also been added.	Firm has submitted a justification that the overage is in accordance with the limits mentioned in the general monographs of USP, however, USP limits for recommended excess volume for 1ml size injection is 0.10ml for Mobile liquids and 0.15ml for Viscous liquid and firm's excess volume does not fall in either of them.
7	Provide evidence of availability of reference product in LPDE ampoule.	Firm has submitted that the same product of contract acceptor has already been registered by the Registration Board in LDPE ampule i.e. Vydee Injection and for which they have submitted the relevant stability study data at the time of its registration.
8	Provide evidence of import/procurement of reference (Indrop-D) product claimed to be utilized for pharmaceutical equivalence studies.	Firm has submitted that they procured the marketed brand Indrop-D from market.
9	Provide evidence of generic/Me-too drug product with same container closure system (LDPE) as claimed for the applied product.	Vydee Injection manufactured by M/s Hudson Pharma Pvt. Ltd.

Decision of PRV meeting: -

The Chairman Registration Board on recommendation of Committee advised to place the case before Registration Board after submission of following by the firm:

S #	Observations	Reply of the firm
1.	Justification for change of container closure system from glass ampoule to LDPE.	The purpose of this change is to meet international standards as well as this change would be beneficial in transportation of material as LDPE (Low Density Polyethylene) ampoules are flexible & non-fragile. On the other hand, it would be better for patients compliance that minimize possible injuries or cuttings, unlike other materials like glass.
2.	Evidence of storage facility for drug substance 'under Nitrogen' condition.	API comes in pouches of 100 grams which usually fully utilized once opened. However, in case any pouch required to be re-sealed then it is done by performing nitrogen purging just after the dispensing procedure.
3.	Real time stability studies data of the registered product (Vydee Injection) of M/s Hudson Pharmaceuticals for its whole claimed shelf life.	Submitted .
4.	Justification of excess fill volume above the limits mentioned in USP general monograph.	A reference from USP CHAPTER 1151submitted wherein 2% excess volume is allowed for mobile liquids.
5.	Capacity Assessment report of contract acceptor M/s. Hudson Pharma Private Limited	The firm submitted Renewal of DML report and claiming it as capacity assessment report

Remarks: The case has been evaluated again and letter of shortcoming has been issued to firm for following points: -

Section	Observations	Reply of the firm
1.3.4	• The inspection report submitted cannot be considered as capacity assessment report. Please submit the capacity assessment report issued by DRAP Regional Office.	The contract acceptor "Husdon Pharma" arranging capacity inspection to their manufacturing facility soon, in the meanwhile we request you to please include our application in the coming DRB agenda.
3.2.P.8	• Please submit supporting data (chromatograms, raw	Submitted

	sheets, calculation sheet) for the stability data of Vyde Injection in LDPE packing.
Decision: Registration Board acceded to the request of the applicant for change in manufacturing site as contract manufacturing along with primary container of the drug product as under: -	
Advit D Injection 200,000IU *(Reg. No. 93025)*	
Existing manufacturing site	**Proposed manufacturing site (Contract Basis)**
M/s Martin Dow Marker Limited (DML# 000028) 7-Jail Road, Quetta. **Primary container:** Glass ampoule	M/s Hudson Pharma Private Limited (DML# 000842) D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75350, Pakistan **Primary container:** LDPE ampoules

Case No. 08: Change of Registration Holder (MA Holder)

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Change of Registration Holder (MA Holder) along with manufacturing site	
	From M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891) Plot No. 710, Sunder Industrial Estate, Lahore	**To M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 27708 dated 27-11-2023
	Details of fee submitted	PKR 30,000/-: dated: 22-09-2023 (Invoice # 64980296996)
	The proposed proprietary name / brand name	**Capsule Dynagab 50 mg *(Reg. # 083776)***
		Initial Registration: 27th March 2017
		Transfer of Registration: *(From Indus to Dynatis)* 24th June 2022
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin ……..……..…50 mg
	Pharmaceutical form of applied drug	Oral Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation

	For generic drugs (me-too status)	**Gabica** approved for M/s Getz
	GMP status of the Finished product manufacturer	**Section:** Capsule (General) Section. **Approval by CLB:** 275th meeting of CLB. **GMP Certificate** issued on the basis of inspection report dated 17th December 2021.
	Name and address of API manufacturer.	M/s Atlas Life Sciences (Private) Limited. C-1/360-361, G.I.D.C. ODHAV, Dist. Ahmedabad, India. **GMP valid till 10-02-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30°C ± 2°C / 65% ± 5% RH for 36 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Gabica 50 mg Capsule **Manufacturer:** Getz Pharma **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Atlas Life Sciences (Private) Limited. C-1/360-361, G.I.D.C. ODHAV, Dist. Ahmedabad, India.
API Lot No.	PG-P1-0860920
Description of Pack (Container closure system)	ALU-ALU Blister Strip, Pack size 2 x 7 capsules
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 18, 42, (Months)		
Batch No.	**DA0036**	**DA0037**	**DA0038**
Batch Size	50000 capsules	50000 capsules	50000 capsules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	10-07-2021	10-07-2021	10-07-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** E-5033/20-21 **Dated:** 09-11-2020 **Quantity:** 100 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Reply of the firm
1.5.6	• Please justify that why innovator specification has been adopted while monograph of BP specification is available in BP Pharmacopeia.	At the time of testing drug product, the monograph was not available in BP Pharmacopeia. However, we are submitting batch analysis report of same stability batches as per BP specifications.
3.2.P.2	• As per DRAP's Guidelines for Post Registration Variation (Ma V - I), please clarify whether there is change in source of API between existing and proposed site of drug manufacturer?	Submitted
	• As per DRAP's Guidelines for Post Registration Variation (Ma V - 3), please submit Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable).	Submitted
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Capsule Dynagab 50 mg *(Reg. # 083776)*

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891) Plot No. 710, Sunder Industrial Estate, Lahore	M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.

7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt) Ltd. (DML # 000124)** **Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Change of Registration Holder (MA Holder)	
	From **M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891)** **Plot No. 710, Sunder Industrial Estate, Lahore**	**To** **M/s Indus Pharma (Pvt) Ltd. (DML # 000124)** **Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 27707 dated 27-11-2023
	Details of fee submitted	PKR 30,000/-: dated: 22-09-2023 (Invoice # 822188806)
	The proposed proprietary name / brand name	**Capsule Dynagab 75 mg *(Reg. # 083777)***
		Initial Registration: 27th March 2017
		Transfer of Registration: *(From Indus to Dynatis)* 24th June 2022
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin ……...……..……75 mg
	Pharmaceutical form of applied drug	Oral Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Gabica** approved for M/s Getz
	GMP status of the Finished product manufacturer	**Section:** Capsule (General) Section. **Approval by CLB:** 275th meeting of CLB. **GMP Certificate** issued on the basis of inspection report dated 17th December 2021.
	Name and address of API manufacturer.	M/s Atlas Life Sciences (Private) Limited. C-1/360-361, G.I.D.C. ODHAV, Dist. Ahmedabad, India. **GMP valid till 10-02-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Gabica 75 mg Capsule **Manufacturer:** Getz Pharma **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Atlas Life Sciences (Private) Limited. C-1/360-361, G.I.D.C. ODHAV, Dist. Ahmedabad, India.		
API Lot No.	PG-P1-0860920		
Description of Pack (Container closure system)	ALU-ALU Blister Strip, Pack size 2 x 7 capsules		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 18, 42, (Months)		
Batch No.	**DB0033**	**DB0034**	**DB0035**
Batch Size	50000 capsules	50000 capsules	50000 capsules
Manufacturing Date	05-2021	06-2021	06-2021
Date of Initiation	10-07-2021	10-07-2021	10-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** E-5033/20-21 **Dated:** 09-11-2020 **Quantity:** 100 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Reply of the firm
1.5.6	• Please justify that why innovator specification has been adopted while monograph of BP specification is available in BP Pharmacopeia.	At the time of testing drug product, the monograph was not available in BP Pharmacopeia. However, we are submitting batch analysis report of same stability batches as per BP specifications.
3.2.P.2	• As per DRAP's Guidelines for Post Registration Variation (Ma V - I), please clarify whether there is change in source of API between existing and proposed site of drug manufacturer?	Submitted
	• As per DRAP's Guidelines for Post Registration Variation (Ma V - 3), please submit Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable).	Submitted
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted

Decision: Registration Board acceded to the request for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Capsule Dynagab 75 mg *(Reg. # 083777)*

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891) Plot No. 710, Sunder Industrial Estate, Lahore	M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Change of Registration Holder (MA Holder)	

	From **M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891)** **Plot No. 710, Sunder Industrial Estate, Lahore**	To **M/s Indus Pharma (Pvt) Ltd. (DML # 000124)** **Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 27707 dated 27-11-2023
	Details of fee submitted	PKR 30,000/-: dated: 22-09-2023 (Invoice # 49347483459)
	The proposed proprietary name / brand name	**Tablet Tofranil 25 mg *(Reg. # 000644)***
		Transfer of Registration: *(From Indus to Dynatis)* 24th June 2022
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar coated tablet contains: Imipramine HCl ……..…….……..…25 mg
	Pharmaceutical form of applied drug	Oral Tablet dosage form
	Pharmacotherapeutic Group of (API)	Tricyclic antidepressants
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	European Medicine Agency approved formulation
	For generic drugs (me-too status)	Imipramine Tablet 25 mg **by Delta Pharma.**
	GMP status of the Finished product manufacturer	**Section:** Tablet (General) Section. **Approval by CLB:** 275th meeting of CLB. **GMP Certificate** issued on the basis of inspection report dated 17th December 2021.
	Name and address of API manufacturer.	M/s Harika Drugs Private Limited. Sy.No.165/A & 165/E, Gummadidala Village, Sangareddy District, Telangana State, Gummadidala (Village), Gummadidala (Mandal), Sangareddy (Dist.), Telangana, India. **GMP valid till 21-11-2025**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 72 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** IMIPRAMINE TABLETS BP 25mg **Manufacturer:** Accord, Barnstaple, EX32 8NS, UK. **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Atlas Life Sciences (Private) Limited. C-1/360-361, G.I.D.C. ODHAV, Dist. Ahmedabad, India.		
API Lot No.	HIHCPN004, HIHCPN001,NIMP/523		
Description of Pack (Container closure system)	Packed in ALU-PVC Blister strips		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 18, 36, (Months)		
Batch No.	**144**	**175**	**108**
Batch Size	750,000 Tablets	750,000 Tablets	750,000 Tablets
Manufacturing Date	11-2019	10-2020	09-2018
Date of Initiation	29-11-2019	13-10-2020	24-09-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dated:**	**Quantity:**
		13-08-2018	250 KG
		03-09-2020	200 KG
		17-09-2019	100 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.	

Remarks of the Evaluator:

Section	Observations	Status
3.2.P.2	• As per DRAP's Guidelines for Post Registration Variation (Ma V - I), please clarify whether there is change in source of API between existing and proposed site of drug manufacturer?	No change
	• As per DRAP's Guidelines for Post Registration Variation (Ma V - 3), please submit Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable).	Submitted
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Tablet Tofranil 25 mg *(Reg. # 000644)*

Existing MAH & manufacturing site	Proposed MAH & manufacturing site
M/s Dynatis Pakistan (Pvt) Ltd. (DML # 000891) Plot No. 710, Sunder Industrial Estate, Lahore	M/s Indus Pharma (Pvt) Ltd. (DML # 000124) Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.

Case No. 09: <u>Change of Registration Holder (MA Holder) along with Change in Manufacturing Site from the already registered drug products on contract basis for "Tablet Cefiget 200 mg". "Capsule Cefiget 400mg" & Cefiget Suspension range.</u>

I	II	III	IV
S. No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
9.	**055746**	**Cefiget Tablets 200mg** Each film-coated tablet contains: Cefixime USP….200mg (as Cefixime trihydrate)	Initial Reg. Date: **14-04-2009** Extension in contract manufacturing till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Opal Laboratories (Pvt.) Ltd. LC-41, L.I.T.E., Landhi, Karachi.

	Name of the Applicant /Market Authorization Holder (existing)	M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Change of Registration Holder (MA Holder) for contract manufacturing to self-manufacturing at another manufacturing site of applicant	
	From	**To**
	Contract manufacturing at: *M/s Opal Laboratories (Pvt.) Ltd.*	**Applied Registration Holder (MA Holder) along with Change in Manufacturing site at:** **M/s Getz Pharma (Pvt.) Ltd. (DML # 000933)** **Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	DRAP has granted new section approval for manufacturing of Cephalosporin products dated 27-02-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Cephalosporin section dated 27-02-2023 specifying Tablet (Cephalosporin), Capsules (Cephalosporin), Dry Powder Suspension (Cephalosporin) & Dry Powder Injection (Cephalosporin) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12965 dated 25-05-2023
	Details of fee submitted	PKR 30,000/- Dated 30.01.2023 (Slip # 4381781510)
	The proposed proprietary name / brand name	**Cefiget Tablets 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Cefixime USP (as Cefixime trihydrate) …. 200mg
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use (Third-generation cephalosporins)
	Pharmaceutical form of applied drug	Light pink colored, oblong shaped, film-coated tablets having bisect line on one side.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5's and 10's
	Proposed unit price	Rs. 294.25/- for 5's and 559.97/- for 10's
	The status in reference regulatory authorities	Cefixime Tablets 200mg by M/s Orchid Europe Limited, UK **(MHRA Approved)**
	For generic drugs (me-too status)	Cefiget Tablets 200mg by M/s Getz Pharma (Pvt.) Ltd., Pakistan. **(Reg. No.: 055746)**

	Name and address of API manufacturer.	**Pharmagen Limited** Kot Nabi Bukshwala, 34 Ferozepur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence study of their product Cefiget Tablets 200mg against the comparator product Cebosh Tablets 200mg by M/s Bosch Pharmaceutical (Pvt.) Ltd., Pakistan by performing quality tests (Appearance, Disintegration time, Average weight, Uniformity of dosage units, water content, Assay & Dissolution). Firm has also submitted Comparative Dissolution Profile studies of their product Cefiget Tablets 200mg against the comparator product Cebosh Tablets 200mg by M/s Bosch Pharmaceutical (Pvt.) Ltd., Pakistan with calculation of f2 value, where applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		**Pharmagen Limited**

		Kot Nabi Bukshwala, 34 Ferozepur Road, Lahore, Pakistan	
API Lot No.		00244/146/2022	
Description of Pack (Container closure system)		Alu-Alu blister.	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		**C027DS01**	**C027DS02**
Batch Size		5000 Tablets	5000 Tablets
Manufacturing Date		11-10-2022	11-10-2022
Date of Initiation		20-10-2022	20-10-2022
No. of Batches		02	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable as DRAP has granted new section approval of Cephalosporin Products (Tablet, Capsules, Dry Powder Suspension & Dry Powder Injection)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 204/2022-DRAP (AD-159531263130-530) dated 22-11-2022 issued by Drug Regulatory Authority of Pakistan. (Valid upto 17-11-2024)	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No.: 75) dated 13-07-2022 specifying purchase of 9Kg of Cefixime (Compacted) from API manufacturer.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator:			
Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: - **Cefiget Tablets 200mg (Reg. # 055746)** **Existing MAH** M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi. **Existing manufacturing site** **Approved MAH & manufacturing site** M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.			

M/s Opal Laboratories (Pvt) Ltd. (DML # 000046)
LC/41 SITE Landhi Karachi.

10.	II	III	IV
	Reg. No.	**Existing Product Name & Composition**	**Registration Trail**
	045118	**Cefiget Capsules 400mg** Each capsule contains: Cefixime USP….400mg (as Cefixime trihydrate)	Initial Reg. Date: **01-02-2007** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Opal Laboratories (Pvt.) Ltd. LC-41, L.I.T.E., Landhi, Karachi.

Name of the Applicant /Market Authorization Holder	M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot No. 29 – 30, Sector 27, Korangi Industrial Area, Karachi
Change of Registration Holder (MA Holder) for contract manufacturing to self-manufacturing at another manufacturing site of applicant	
From	**To**
Contract manufacturing at: *M/s Opal Laboratories (Pvt.) Ltd.*	**Change of Registration Holder (MA Holder) along with Change in Manufacturing site at:** M/s Getz Pharma (Pvt.) Ltd. **(DML # 000933)** Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	DRAP has granted new section approval for manufacturing of Cephalosporin products dated 27-02-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Cephalosporin section dated 27-02-2023 specifying Tablet (Cephalosporin), Capsules (Cephalosporin), Dry Powder Suspension (Cephalosporin) & Dry Powder vial Injection (Cephalosporin) sections.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No 13458 dated 30.05.2023
Details of fee submitted	PKR 30,000/- Dated 30.05.2023 (Slip # 7985149810)
The proposed proprietary name / brand name	**Cefiget Capsules 400mg**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime USP (as Cefixime trihydrate) …. 400mg
Pharmacotherapeutic Group of (API)	Anti-infective for Systemic use (J01DD08)

	Pharmaceutical form of applied drug	Hard gelatin capsules containing white to light yellow free flowing powder.
	Reference to Finished product specifications	DRAP Specification
	Proposed Pack size	5's
	Proposed unit price	Rs. 511.19/- for 5's
	The status in reference regulatory authorities	SUPRAX Capsules 400mg by M/s Lupin Limited, USA. **(USFDA Approved)**
	For generic drugs (me-too status)	Cefiget Capsules 400mg by M/s Getz Pharma (Pvt.) Ltd., Pakistan. **(Reg. No.: 045118)**
	Name and address of API manufacturer.	**Pharmagen Limited** Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence study of their product Cefiget Capsules 400mg against the comparator product Cefspan Capsules 400mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Pakistan by performing quality tests (Appearance, Disintegration time, Average weight of content, Uniformity of dosage units, water content, Assay, Dissolution & Related

		Substances). Firm has also submitted Comparative Dissolution Profile studies of their product Cefiget Capsules 400mg against the comparator product Cefspan Capsules 400mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Pakistan with calculation of f2 value, where applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	**Pharmagen Limited** Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore, Pakistan	
API Lot No.	00244/146/2022	
Description of Pack (Container closure system)	Hard gelatin capsules containing white to light yellow free flowing powder, packed in Alu-Alu blister.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	**C028DS01**	**C028DS02**
Batch Size	5000 capsules	5000 capsules
Manufacturing Date	12-10-2022	12-10-2022
Date of Initiation	20-10-2022	20-10-2022
No. of Batches	02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable as DRAP has granted new section approval of Cephalosporin Products (Tablet, Capsules, Dry Powder Suspension & Dry Powder vial Injection)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 204/2022-DRAP (AD-159531263130-530) dated 22-11-2022 issued by Drug Regulatory Authority of Pakistan. (Valid upto 18-11-2024)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No.: 75) dated 13-07-2022 specifying purchase of 9Kg of Cefixime (Compacted) from API manufacturer.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Cefiget Capsules 400mg (Reg. # 045118)

Existing MAH	**Approved MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.
Existing manufacturing site	
M/s Opal Laboratories (Pvt) Ltd. (DML # 000046) LC/41 SITE Landhi Karachi.	

11.

Reg. No	**Existing Product Name & Composition**	**Registration Trail**
045119	**Cefiget Powder for Oral Suspension 100mg/5mL** Each reconstituted 5mL contains: Cefixime USP … 100mg (As Cefixiome trihydrate)	Initial Reg. Date: **01.02.2007** Extension in contract manufacturing till **30-06-2025** (issued vide letter dated 12-08-2020) **Contract manufacturing at:** M/s Opal Laboratories (Pvt.) Ltd, LC-41., L.I.T.E, Landhi, Karachi.

Name of the Applicant / Market Authorization Holder	M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi

Change of Registration Holder (MA Holder) for contract manufacturing to self-manufacturing at another manufacturing site of applicant.

From	**To**
Contract manufacturing at: M/s Opal Laboratories (Pvt.) Ltd, LC-41., L.I.T.E, Landhi, Karachi.	**Change of Registration Holder (MA Holder) along with Change in Manufacturing site at:** M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	DRAP has granted new section approval for manufacturing of Cephalosporin products dated 27-02-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of Cephalosporin section dated 27-02-2023 specifying Tablets (Cephalosporin), Capsules (Cephalosporin), Dry Powder Suspension (Cephalosporin) & Dry Powder Injection (Cephalosporin) sections.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 12963 dated 25-05-2023
	Details of fee submitted	PKR 30,000/- Dated 30.01.2023 (84598733492)
	The proposed proprietary name / brand name	**Cefiget Powder for Oral Suspension 100mg/5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5mL contains: Cefixime USP (As Cefixime trihydrate)…… 100mg
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use (Third-generation cephalosporins)
	Pharmaceutical form of applied drug	White to cream color free flowing granular powder filled in HDPE plastic bottle.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	30mL and 60mL
	Proposed unit price	Rs. 285.27/- for 30mL Rs. 559.13/- for 60mL
	The status in reference regulatory authorities	Cefixime Suspension 100mg/5mL by M/s Aurbindo Pharma Ltd., USA. **(USFDA Approved)**
	For generic drugs (me-too status)	Cefiget Powder for Oral Suspension 100mg/5mL by M/s Getz Pharma (Pvt.) Ltd., Pakistan. **(Reg. No.: 045119)**
	Name and address of API manufacturer.	**M/s Pharmagen Ltd.** Kot Nabi Bukhsh Wala, 34-km, Ferozepur Road, Lahore – Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence study of their product **Cefiget Powder for Oral Suspension 100mg/5mL** against the comparator product **Cefspan Suspension 100mg/5mL** by **M/s Barrett Hodgson Pakistan (Pvt.) Ltd.**
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	**M/s Pharmagen Ltd.** Kot Nabi Bukhsh Wala, 34-km, Ferozepur Road, Lahore – Pakistan.	
API Lot No.	00243/146/2022	
Description of Pack (Container closure system)	HDPE Plastic Bottle	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	**C024DS01**	**C024DS02**
Batch Size	2000 bottles	2000 bottles
Manufacturing Date	06.10.2022	06.10.2022
Date of Initiation	20.10.2022	20.10.2022
No. of Batches	02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable as DRAP has granted new section approval of Cephalosporin Products (Tablets, Capsules, Dry Powder Suspension & Dry Powder Injection).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. 204/2022-DRAP (AD/159531263130-530) dated 22.11.2022 issued by Drug Regulatory Authority of Pakistan (Valid upto 17.11.2024).

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No.: 75 dated 13-07-2022 for 14kg of Cefixime (Micronized) from API manufacturer.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Cefiget Powder for Oral Suspension 100mg/5mL (Reg. # 045119)

Existing MAH	**Approved MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

Existing manufacturing site

M/s Opal Laboratories (Pvt) Ltd. (DML # 000046)
LC/41 SITE Landhi Karachi.

12.	**Reg. No**	**Existing Product Name & Composition**	**Registration Trail**
	045120	**Cefiget DS Powder for Oral Suspension 200mg/5mL** Each reconstituted 5mL contains: Cefixime USP … 200mg (As Cefixime trihydrate)	Initial Reg. Date: **01.02.2007** Extension in contract manufacturing till **30-06-2025** (issued vide letter dated 12-08-2020) **Contract manufacturing at:** M/s Opal Laboratories (Pvt.) Ltd, LC-41., L.I.T.E, Landhi, Karachi.

Name of the Applicant /Market Authorization Holder	M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
Change of Registration Holder (MA Holder) for contract manufacturing to self-manufacturing at another manufacturing site of applicant	
From	**To**
Contract manufacturing at: M/s Opal Laboratories (Pvt.) Ltd, LC-41., L.I.T.E, Landhi, Karachi.	**Change of Registration Holder (MA Holder) along with Change in Manufacturing site at:** M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	DRAP has granted new section approval for manufacturing of Cephalosporin products dated 27-02-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Cephalosporin section dated 27-02-2023 specifying

		Tablet (Cephalosporin), Capsules (Cephalosporin), Dry Powder Suspension (Cephalosporin) & Dry Powder Injection (Cephalosporin) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 12964 dated 25-05-2023
	Details of fee submitted	PKR 30,000/- Dated 30.01.2023
	The proposed proprietary name / brand name	**Cefiget DS Powder for Oral Suspension 200mg/5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5mL contains: Cefixime USP … 200mg (As Cefixime trihydrate)
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use (Third-generation cephalosporins)
	Pharmaceutical form of applied drug	White to cream color free flowing granular powder filled in HDPE plastic bottle.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	30mL
	Proposed unit price	Rs. 349.12/- for 30mL
	The status in reference regulatory authorities	Cefixime Suspension 200mg/5mL by M/s Aurbindo Pharma Ltd., USA. **(USFDA Approved)**
	For generic drugs (me-too status)	Cefiget DS Powder for Oral Suspension 200mg/5mL by M/s Getz Pharma (Pvt.) Ltd., Pakistan. **(Reg.No. 045120)**
	Name and address of API manufacturer.	**M/s Pharmagen Ltd.** Kot Nabi Bukhsh Wala, 34-km, Ferozepur Road, Lahore – Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence study of their product **Cefiget DS Powder for Oral Suspension 200mg/5mL** against the comparator product **Cefspan DS Suspension 200mg/5mL** by **M/s Barrett Hodgson Pakistan (Pvt.) Ltd.**
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	**M/s Pharmagen Ltd.** Kot Nabi Bukhsh Wala, 34-km, Ferozepur Road, Lahore – Pakistan.	
API Lot No.	00243/146/2022	
Description of Pack (Container closure system)	HDPE Plastic Bottle	
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	**C026DS01**	**C026DS02**
Batch Size	2000 bottles	2000 bottles
Manufacturing Date	10.10.2022	10.10.2022
Date of Initiation	20.10.2022	20.10.2022
No. of Batches	02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable as DRAP has granted new section approval of Cephalosporin Products (Tablets, Capsules, Dry Powder Suspension & Dry Powder Injection)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. 204/2022-DRAP (AD/159531263130-530) dated 22.11.2022 issued by Drug Regulatory Authority of Pakistan **(Valid upto 17.11.2024)**

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No.: 75 dated 13-07-2022 for 14Kg of Cefixime (Micronized) from API manufacturer
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: - **Cefiget DS Powder for Oral Suspension 200mg/5mL (Reg. # 045120)** **Existing MAH** / **Approved MAH & manufacturing site** M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi. / M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi. **Existing manufacturing site** M/s Opal Laboratories (Pvt) Ltd. (DML # 000046) LC/41 SITE Landhi Karachi.		

Case No. 10: **<u>Change of Registration Holder (MA Holder) along with Change in Manufacturing Site for the registered drug product "Tablet Diampa-M" in strength of 5/850, 12.5/850 & 12.5/500.</u>**

13.	**Name, address of Applicant / Marketing Authorization Holder.**	**M/s Getz Pharma (Pvt) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi**
	Change of Registration Holder (MA Holder)	
	From	**To**
	M/s Getz Pharma (Pvt) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	**Change of Registration Holder (MA Holder) along with Change in Manufacturing site at: M/s Getz Pharma (Pvt) Ltd (DML # 000933) Plot # 01, Sector 25, Korangi Industrial Area, Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.: 28257 dated 06-12-2023
	Details of fee submitted	PKR 30,000/-: 06.12.2023 *(Slip # 7061749134)*

The proposed proprietary name / brand name	**Diampa-M Tablets 5mg + 500mg** **Registration No.:** 105287 **Initial registration:** 19-10-2020 **Renewal Status:** Not yet due
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin…….5mg Metformin HCl USP……500mg
Pharmaceutical form of applied drug	Film-coated Tablets
Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	14's
Proposed unit price	Rs. 636.28/- (14's)
The status in reference regulatory authorities	Synjardy 5mg + 500mg Tablet by M/s Boehringer Ingelheim, USA. USFDA Approved.
For generic drugs (me-too status)	Diampa-M Tablets 5mg + 500mg (Reg. No.: 105287) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi.
Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Empagliflozin: Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Metformin HCl: Official monograph of Metformin HCl is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

	standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: <u>Empagliflozin:</u> Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04) <u>Metformin HCl:</u> Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-72611405016, A-72611405017,A-72611405018)
Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt.) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Diampa-M Tablets 5mg + 500mg against the reference product Jardiance Duo Tablets 5mg/500mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), in three dissolution mediums wherein more than 85% of drug is released in 15 minutes. Pharmaceutical Equivalence Studies of Diampa-M Tablets 5mg + 500mg against the reference product Jardiance Duo Tablets 5mg/500mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), by performing quality tests (Appearance, Identification, Assay, Dissolution and Related substances). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Diampa-M Tablets 5mg + 500mg (new site) against the reference product Diampa-M Tablets 5mg + 500mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions form existing manufacturing site and stability studies of two batches from new manufacturing site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

	Empagliflozin:
Manufacturer of APIs	<u>Jiangsu Yongan Pharmaceutical Co., Ltd.</u> No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development, Jiangsu, China.

API Lot No.	**Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China. Empagliflozin: 0000182058 Metformin HCl: 0000182022, 0000182024		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**001FC1**	**002FC1**	**003FC1**
Batch Size	200,000 Tablets	200,000 Tablets	200,000 Tablets
Manufacturing Date	03-11-2020	10.11.2020	11.11.2020
Date of initiation	24.12.2020	24.12.2020	24.12.2020
No. of Batches		03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. Related manufacturing area, equipment, personnel and utilities are in compliance.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: Copy of Drug Manufacturing License no. Su 20160324 issued by Jiangsu Drug Administration (Huai'an Inspection Branch) valid till 06-12-2025. Metformin HCl: Copy of GMP Certificate No. SD20190888 issued by China food and Drug Administration (CFDA), China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
20200902	JXCAVIR-200504	30kg	18-09-2020

Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
A-81412006068	JC20203027-3	2000Kg	28-08-2020
A-81412006070	JC20203027-3	2000Kg	28-08-2020

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

Manufacturer of APIs	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.		
API Lot No.	Empagliflozin: 0000213732 Metformin HCl: 0000211608		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 0, 3 , 6 (Months) Real Time: 0, 3, 6 (Months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	065ES01	065ES02	-

Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	06.01.2023	06.01.2023	-
Date of initiation	27.01.2023	27.01.2023	-
No. of Batches		02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any)

   Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25 Korangi Industrial Area, Karachi is a new License facility hence no such inspection has been conducted (existing inspection)

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

   Empagliflozin: Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 17-11-2027.

   Metformin HCl: Copy of GMP Certificate No. SD20190888 issued by China food and Drug Administration (CFDA), China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

   Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

   Empagliflozin:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
H-CP035220901C	HN20220818-E-1	32 Kg	17.10.2022

   Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
A-22612205091-0150	JC202203068-1	2000 kg	28.07.2022

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

   Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

   Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

   Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

Firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.

- Stability Data of 2 stability batches at initial, 3rd month and 6th month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator product from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP/DML of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Diampa-M Tablets 5mg + 500mg (Reg. # 105287)

Existing MAH & manufacturing site	Approved MAH & manufacturing site
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

14. Name, address of Applicant / Marketing Authorization Holder. **M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.**

Change of Registration Holder (MA Holder)

From	To
M/s Getz Pharma (Pvt) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.**
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No.: 28259 dated 06-12-2023
Details of fee submitted	PKR 30,000/-: 03.10.2023 *(Slip # 1283520543)*
The proposed proprietary name / brand name	**Diampa-M Tablets 12.5mg + 500mg** **Registration No.:** 105551 **Initial registration:** 28th December 2020 **Renewal status:** not yet due
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….12.5mg Metformin HCl USP….500mg

Pharmaceutical form of applied drug	Film-coated Tablets
Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	14's
Proposed unit price	Rs. 615.04/- (14's)
The status in reference regulatory authorities	Synjardy 12.5mg + 500mg Tablet by M/s Boehringer Ingelheim Pharmaceuticals, USA. USFDA Approved.
For generic drugs (me-too status)	Diampa-M Tablets 12.5mg + 500mg (Reg. No.: 105551) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi.
Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Empagliflozin: Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Metformin HCl: Official monograph of Metformin HCl is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Empagliflozin: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

	Batches: (L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04) <u>Metformin HCl:</u> Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-72611405016, A-72611405017,A-72611405018)
Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt.) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 500mg against the reference product Jardiance Duo Tablets 12.5mg/500mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), in three dissolution mediums wherein more than 85% of drug is released in 15 minutes. Pharmaceutical Equivalence Studies of Diampa-M Tablets 12.5mg + 500mg against the reference product Jardiance Duo Tablets 12.5mg/500mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), by performing quality tests (Appearance, Assay, Dissolution, Identification & Related Substances). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 500mg (new site) against the reference product Diampa-M Tablets 12.5mg + 500mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions form existing manufacturing site and stability studies of two batches from new manufacturing site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

Manufacturer of APIs	**Empagliflozin:** <u>Fuxin Long Rui Pharmaceutical Co., Ltd.</u> Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** <u>Shouguang Fukang Pharmaceutical Co., Ltd.</u>

	North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.		
API Lot No.	Empagliflozin: 0000183890 Metformin HCl: 0000183290, 0000184464		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**001FE9**	**002FE9**	**003FE9**
Batch Size	325,000 Tablets	325,000 Tablets	325,000 Tablets
Manufacturing Date	31.12.2020	14.01.2021	15.01.2021
Date of initiation	18.02.2021	27.04.2021	27.04.2021
No. of Batches		03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. Related manufacturing area, equipment, personnel and utilities are in compliance.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>Empagliflozin:</u> Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 17-11-2027. <u>Metformin HCl:</u> Copy of GMP Certificate No. SD20190888 issued by China Food & Drug Administration (CFDA), China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
L-E-20200629-D02-E06-01	HN20201111-1	50kg	20-11-2020

Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
A-32612008049	JC20203027-4	2000Kg	06-10-2020
A-32612009029	JC20204015-1	2000Kg	26-10-2020

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

Manufacturer of APIs	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
API Lot No.	Empagliflozin: 0000213732 Metformin HCl: 0000211608
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Accelerated: 0, 3 , 6 (Months) Real Time: 0, 3, 6 (Months)
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	064ES01	064ES02	-
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	02-01-2023	02-01-2023	-
Date of initiation	27.01.2023	27.01.2023	-
No. of Batches		02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any)

Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25 Korangi Industrial Area, Karachi is a new License facility hence no such inspection has been conducted (existing inspection)

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Empagliflozin: Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 17-11-2027.

Metformin HCl: Copy of GMP Certificate No. SD20190888 issued by China Food & Drug Administration (CFDA),, China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
H-CP035220901C	HN20220818-E-1	32 Kg	17.10.2022

Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
A-22612205091-0150	JC202203068-1	2000 kg	28.07.2022

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial, 3rd month and 6th month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial

Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.

- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator product from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP/DML of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Diampa-M Tablets 12.5mg + 500mg (Reg. # 105551)

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

15.	**Name, address of Applicant / Marketing Authorization Holder.**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.**
	Change of Registration Holder (MA Holder)	
	From	**From**
	M/s Getz Pharma (Pvt) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.: 28259 dated 06-12-2023
	Details of fee submitted	PKR 30,000/-: 03.10.2023 *(Slip # 4520785148)*
	The proposed proprietary name / brand name	**Diampa-M Tablets 12.5mg + 850mg** **Registration No.:** 1055552 **Initial Registration:** 28th December 2020 **Renewal Status:** not yet due
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….12.5mg Metformin HCl USP….850mg

Pharmaceutical form of applied drug	Film-coated Tablets
Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	14's
Proposed unit price	Rs. 624.33/- (14's)
The status in reference regulatory authorities	Synjardy 12.5mg + 850mg Tablet by M/s Boehringer Ingelheim Pharmaceuticals, Australia. TGA Approved.
For generic drugs (me-too status)	Diampa-M Tablets 12.5mg + 850mg (Reg. No.: 105552) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Empagliflozin: Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Metformin HCl: Official monograph of Metformin HCl is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Empagliflozin: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

	Batches: (L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04) <u>Metformin HCl:</u> Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-72611405016, A-72611405017,A-72611405018)
Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt.) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 500mg against the reference product Jardiance Duo Tablets 12.5mg/1000mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), in three dissolution mediums wherein more than 85% of drug is released in 15 minutes. Pharmaceutical Equivalence Studies of Diampa-M Tablets 12.5mg + 500mg against the reference product Jardiance Duo Tablets 12.5mg/1000mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), by performing quality tests (Appearance, Assay, Dissolution, Identification & Related Substances). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 850mg (new site) against the reference product Diampa-M Tablets 12.5mg + 850mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions form existing manufacturing site and stability studies of two batches from new manufacturing site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

Manufacturer of APIs	**Empagliflozin:** <u>Fuxin Long Rui Pharmaceutical Co., Ltd.</u> Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** <u>Shouguang Fukang Pharmaceutical Co., Ltd.</u> North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
API Lot No.	Empagliflozin:

	0000183890 Metformin HCl: 0000183290, 0000183292, 0000184462, 0000184464
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	**001FF1**	**002FF1**	**003FF1**
Batch Size	190,000 Tablets	190,000 Tablets	190,000 Tablets
Manufacturing Date	31.12.2020	14.01.2021	15.01.2021
Date of initiation	18.02.2021	27.04.2021	27.04.2021
No. of Batches		03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any)

Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:

- The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
  - ✓ Have Audit trail
  - ✓ Have backup system
  - ✓ Have Data traceability
  - ✓ Have Data achieving system
  - ✓ Have data integrity
  - ✓ Have Data security
  - ✓ System Security Policy
- Audit trail on the testing reports is available.
- Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.

Related manufacturing area, equipment, personnel and utilities are in compliance.

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Empagliflozin: Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 17-11-2027.

Metformin HCl: Copy of GMP Certificate No. SD20190888 issued by China Food & Drug Administration (CFDA), China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRA**

L-E-20200629-D02-E06-01	HN20201111-1	50kg	20-11-2020

Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date approv by DR
A-32612008049	JC20203027-4	2000Kg	06-10-2
A-32612008060	JC20203027-4	2000Kg	06-10-2
A-32612009092	JC20204015-1	2000Kg	26-10-2
A-32612009029	JC20204015-1	2000Kg	26-10-2

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

Manufacturer of APIs	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.		
API Lot No.	Empagliflozin: 0000213732 Metformin HCl: 0000211608		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 0, 3 , 6 (Months) Real Time: 0, 3, 6 (Months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	066ES01	066ES02	-
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	10-01-2023	10-01-2023	-
Date of initiation	02.02.2023	02.02.2023	-
No. of Batches		02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any)

Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25 Korangi Industrial Area, Karachi is a new

License facility hence no such inspection has been conducted (existing inspection)

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Empagliflozin: Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 17-11-2027.

Metformin HCl: Copy of GMP Certificate No. SD20190888 issued by China Food & Drug Administration (CFDA), China valid till 12-03-2024.

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
H-CP035220901C	HN20220818-E-1	32 Kg	17.10.2022

Metformin HCl:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
A-22612205091-0150	JC202203068-1	2000 kg	28.07.2022

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial, 3rd month and 6th month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator product from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.

- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP/DML of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Diampa-M Tablets 12.5mg + 850mg (Reg. # 105552)

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

Case No. 11: Change of Registration Holder (MA Holder) <u>along with Change in Manufacturing Site for the registered drug product "Tablet Starcox" in strength of 60mg , 90mg & 120mg.</u>

16.	**Name of the Applicant /Market Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd (DML # 000284)** **Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi**
	Change of Registration Holder (MA Holder)	
	From	**To**
	M/s Getz Pharma (Pvt) Ltd (DML # 000284) **Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.**	**Change of Registration Holder (MA Holder) along with Change in Manufacturing site at:** **M/s Getz Pharma (Pvt) Ltd (DML # 000933)** **Plot # 01, Sector 25, Korangi Industrial Area, Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27291 (dated: 20-11-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-05-2022 (Invoice # 6975739482)
	The proposed proprietary name / brand name	Starcox Tablets 60mg **Registration No.:** 075969 **Initial registration:** 30th May 2013 **Renewal Status:** application submitted within time.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Etoricoxib… 60mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory and Antirheumatic product, non-steroid, coxib
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's
	Proposed unit price	Rs. 212.93 for 10's

	The status in reference regulatory authorities	Arcoxia (Etoricoxib) Tablets 60mg by Organon Pharma (UK) Limited UK **MHRA approved**
	For generic drugs (me-too status)	Starcox Tablets 60mg (Reg. No.: 075969) by M/s Getz Pharma (Pvt.) Limited
	GMP status of the Finished product manufacturer	Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.	**M/s Glenmark Life Sciences Limited.** Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. (Batch No.: 071400955, 071400969, 071400979)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Starcox Tablets 60mg against the reference product Arcoxia Tablets 60mg by M/s Merck Sharp & Dohme Greece, in three dissolution mediums has been submitted with acceptable level of f2 results. Pharmaceutical Equivalence Studies of Starcox Tablets 60mg against the reference product Arcoxia Tablets 60mg by M/s Merck Sharp & Dohme Greece, by performing quality tests (Appearance, Average weight, Assay and Dissolution).

		Getz Pharma (Pvt) Limited **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Starcox Tablets 60mg (New Site) against the reference product Starcox Tablets 60mg (Existing Site) in routine release Medium.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)			
Manufacturer of API	M/s. Glenmark Life Sciences Limited. Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.		
API LOT #	Getz Pharma Batch No. 0000179979, 0000184314 & 0000184316 Glenmark Batch No. 85200030, 85200044 & 85200077		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	204F79	205F79	206F79
Batch Size	700,000 Tablets	700,000 Tablets	700,000 Tablets
Manufacturing Date	05-01-2021	17-02-2021	17-02-2021
Date of Initiation	18-02-2021	23-06-2021	23-06-2021
No. of Batches	03		

Administrative Portion		
i.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy

<table>
<tr><td></td><td></td><td colspan="4">• Audit trail on the testing reports is available.
• Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
Related manufacturing area, equipment, personnel and utilities are in compliance.</td></tr>
<tr><td>ii.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="4">Firm has submitted copy of GMP certificate No.: NEW-WHO-GMP/CERT/PD/104460/2021/11/36840 issued by Food and Drug Administration, Maharashtra State, India is valid till 29.07.2024.</td></tr>
<tr><td>iii.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="4">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>85200030</td><td>F300000000298</td><td>100.0kg</td><td>20-07-2020</td></tr><tr><td>85200044</td><td>F300000001194</td><td>125.0kg</td><td>10-12-2020</td></tr><tr><td>85200077</td><td>F300000001194</td><td>125.0kg</td><td>10-12-2020</td></tr></table></td></tr>
<tr><td>iv.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="4">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>v.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td colspan="4">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>vi.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="4">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="6">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="4">M/s. Glenmark Life Sciences Limited.
Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="4">Getz Pharma Batch No.
0-196578

Glenmark Batch No.
85210041</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="4">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="4">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="4">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="4">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>038ES01</td><td>038ES02</td><td colspan="2">-</td></tr>
</table>

Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	17.01.2022	17.01.2022	-
Date of initiation	24.01.2022	24.01.2022	-
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any) — NA
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. — Firm has submitted copy of GMP certificate No.: **NEW-WHO-GMP/CERT/PD/104460/2021/11/36840** issued by Food and Drug Administration, Maharashtra State, India is valid till **29.07.2024.**
3. Documents for the procurement of API with approval from DRAP (in case of import). — Copy of invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
85210041	F32200000766	125kg	21.10.2021

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. — Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing. — Firm has submitted compliance certificate of HPLC software.
6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) — Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial, 3rd and 6th time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against reference product from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP Certificate of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Starcox Tablets 60mg (Reg. # 075969)

Existing MAH & manufacturing site	Proposed MAH & manufacturing site
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

17.	**Name, address of Applicant / Marketing Authorization Holder.**	**M/s Getz Pharma (Pvt.) Ltd.** **Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan (DML # 000933)**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.:
	Details of fee submitted	PKR 30,000/-: 17-05-2022
	The proposed proprietary name / brand name	**Starcox Tablets 90mg** **Registration No.:** 105293 **Initial registration:** 19th October 2020 **Renewal Status:** not yet due
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Etoricoxib… 90mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory and Antirheumatic product, non-steroid, coxib
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's and 14's
	Proposed unit price	23.96 for 1's and 337.81 for 14's
	The status in reference regulatory authorities	Arcoxia (Etoricoxib) Tablets 90mg by Organon Pharma (UK) Limited UK **MHRA approved**
	For generic drugs (me-too status)	Starcox Tablets 90mg (Reg. No.: 105293) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**M/s Glenmark Life Sciences Limited.** Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

	specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. (Batch No.: 071400955, 071400969, 071400979)
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Starcox Tablets 90mg against the reference product Arcoxia Tablets 90mg by M/s Merck Sharp & Dohme BV, Netherland, in three dissolution mediums has been submitted with acceptable level of f2 results. Pharmaceutical Equivalence Studies of Starcox Tablets 90mg against the reference product Arcoxia Tablets 90mg by M/s Merck Sharp & Dohme BV, Netherland, by performing quality tests (Appearance, Average weight, Assay and Dissolution). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Starcox Tablets 90mg (New Site) against the reference product Starcox Tablets 90mg (Existing Site) in routine release Medium.
Analytical method validation/ verification of product	Firm has submitted validation studies of the drug product.
Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

	M/s. Glenmark Life Sciences Limited.
Manufacturer of APIs	Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.
API Lot No.	Getz Pharma Batch No. 0000175902 & 0000179975

	Glenmark Batch No. 85200001 & 85200035		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	001FE7	002FE7	003FE7
Batch Size	475,000 Tablets	475,000 Tablets	475,000 Tablets
Manufacturing Date	20.10.2020	02.11.2020	02.11.2020
Date of initiation	02.12.2020	22.01.2021	22.01.2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: Have Audit trail Have backup system Have Data traceability Have Data achieving system Have data integrity Have Data security System Security Policy Audit trail on the testing reports is available. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. Related manufacturing area, equipment, personnel and utilities are in compliance.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No.: **NEW-WHO-GMP/CERT/PD/104460/2021/11/36840** issued by Food and Drug Administration, Maharashtra State, India is valid till **29.07.2024.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRAP**
85200001	F30000001521	100.0 kg	27.03.2020
85200035	F30000000298	125.0kg	20.07.2020

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

	M/s. Glenmark Life Sciences Limited.		
Manufacturer of APIs	Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.		
API Lot No.	Getz Pharma Batch No. 0-196578 Glenmark Batch No. 85210041		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	039ES01	039ES02	-
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	17.01.2022	17.01.2022	-
Date of initiation	28.01.2022	28.01.2022	-
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No.: **NEW-WHO-GMP/CERT/PD/104460/2021/11/36840** issued by Food and Drug Administration, Maharashtra State, India is valid till **29.07.2024.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRAP**
85210041	F32200000766	125 kg	21.10.2021

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

Firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:
Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
Stability Data of 2 stability batches at initial, 3rd and 6th time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against reference product from new manufacturing facility.
Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
Firm has submitted Executed Production document of stability batch.
Firm has submitted Process Validation Protocol.
Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
Analytical Method Verification / validation studies of API & Finished product.
Valid GMP Certificate of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Starcox Tablets 90mg (Reg. # 105293)

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

18.	**Name, address of Applicant / Marketing Authorization Holder.**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.:
	Details of fee submitted	PKR 30,000/-: 17-05-2022
	The proposed proprietary name / brand name	**Starcox Tablets 120 mg** **Registration No.:** 105294 **Initial registration:** 19th October 2020 **Renewal Status:** not yet due
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Etoricoxib… 120mg

Pharmaceutical form of applied drug	Film-coated Tablets
Pharmacotherapeutic Group of (API)	Anti-Inflammatory and Antirheumatic product, non-steroid, coxib
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	1's & 7's
Proposed unit price	Rs. 31.62 for 1's & Rs. 212.75 for 7's
The status in reference regulatory authorities	Arcoxia (Etoricoxib) Tablets 120mg by Organon Pharma (UK) Limited UK **MHRA approved**
For generic drugs (me-too status)	Starcox Tablets 120mg (Reg. No.: 105294) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
Name and address of API manufacturer.	**M/s Glenmark Life Sciences Limited.** Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. (Batch No.: 071400955, 071400969, 071400979)
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Starcox Tablets 120mg against the reference product Arcoxia Tablets 120mg by M/s Merck Sharp & Dohme BV

	Netherland, in three dissolution mediums has been submitted with acceptable level of f2 results. Pharmaceutical Equivalence Studies of Starcox Tablets 120mg against the reference product Arcoxia Tablets 120mg by M/s Merck Sharp & Dohme BV Netherland, by performing quality tests (Appearance, Average weight, Assay and Dissolution). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Starcox Tablets 120mg (New Site) against the reference product Starcox Tablets 120mg (Existing Site) in routine release Medium.
Analytical method validation/ verification of product	Firm has submitted validation studies of the drug product.
Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

	M/s. Glenmark Life Sciences Limited.		
Manufacturer of APIs	Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.		
API Lot No.	Getz Pharma Batch No. 0000175902, 0000179975, 0000179979, 0000184315 & 0000184316		
	Glenmark Batch No. 85200001, 85200035, 85200030, 85200076, 85200077		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	001FE8	002FE8	003FE8
Batch Size	340,000 Tablets	340,000 Tablets	340,000 Tablets
Manufacturing Date	20-10-2020	02-11-2020	05-01-2021
Date of initiation	02-12-2020	12-02-2021	18-02-2021
No. of Batches		03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability

- ✓ Have Data achieving system
- ✓ Have data integrity
- ✓ Have Data security
- ✓ System Security Policy

- Audit trail on the testing reports is available.
- Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
- Related manufacturing area, equipment, personnel and utilities are in compliance.

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Firm has submitted copy of GMP certificate No.: **NEW-WHO-GMP/CERT/PD/104460/2021/11/36840** issued by Food and Drug Administration, Maharashtra State, India is valid till **29.07.2024.**

3. Documents for the procurement of API with approval from DRAP (in case of import).

Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
85200001	F30000001521	100.0kg	27-03-2020
85200035	F30000000298	125.0kg	20-07-2020
85200030	F30000000298	100.0kg	20-07-2020
85200076	F30000001194	75.0kg	10-12-2020
85200077	F30000001194	125.0kg	10-12-2020

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

	M/s. Glenmark Life Sciences Limited.
Manufacturer of APIs	Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakri Audyogik Vasahat Maryadit., Pune-Hyderabad Highway, Mohol Solapur - 413213, Maharashtra State, India.
API Lot No.	Getz Pharma Batch No. 0-196578 Glenmark Batch No. 85210041
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)
Batch No.	040ES01 040ES02 -

Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	17.01.2022	17.01.2022	-
Date of initiation	28.01.2022	28.01.2022	-
No. of Batches		02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1. Reference of previous approval of applications with stability study data of the firm (if any) — NA

2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. — Firm has submitted copy of GMP certificate No.: **NEW-WHO-GMP/CERT/PD/104460/2021/11/36840** issued by Food and Drug Administration, Maharashtra State, India is valid till **29.07.2024.**

3. Documents for the procurement of API with approval from DRAP (in case of import). — Copy of invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
85210041	F32200000766	125kg	21.10.2021

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. — Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.

5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing. — Firm has submitted compliance certificate of HPLC software.

6. Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) — Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of the Evaluator:

firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial, 3rd and 6th time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against reference product from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP Certificate of the API manufacturer submitted.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Starcox Tablets 120mg (Reg. # 105294)

Existing MAH & manufacturing site	Proposed MAH & manufacturing site
M/s Getz Pharma (Pvt.) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Getz Pharma (Pvt.) Ltd. (DML # 000933) Plot No. 01, Sector 25, Korangi Industrial Area, Karachi.

Case No. 12: Change of Registration Holder (MA Holder) along with Change in manufacturing site of Tablet PRAZ.

19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.**
	Change of Registration Holder (MA Holder) along with change of Manufacturing Site	
	From M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.	**To M/s Scilife Pharma (Pvt) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track U8P-JYD-65AH Dated : 21-05-2024
	Details of fee submitted	PKR 30,000/-: 27-02-2024 (Slip # 978372686189)
	The proposed proprietary name / brand name	**Tablet PRAZ 1 mg (*Reg. # 028697)*** **Initial Registration:** 08-11-2002 **Change of brand name:** 03-06-2003 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Alprazolam ……. 1mg
	Pharmacotherapeutic Group of (API)	Benzodiazepines derivatives
	Reference to Finished product specifications	USP Specification
EVALUATION OF DATA		
GMP status of the firm		**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 22-02-2023.
Evidence of approval of manufacturing facility		**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the grant of additional section **Tablet (Psychotropic) Section.**
Proposed Pack size		Proposed Pack size: 10's, 30's, 50's & 100's
Proposed unit price		As per SRO
The status in reference regulatory authorities		USFDA approved formulation
For generic drugs (me-too status)		Azolam 1 mg tablet by Martin Dow
Name and address of API manufacturer.		CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 - 20067 PAULLO (MI) – Italy.

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 12 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet PRAZ 1mg **Manufacturer:** Getz Pharma **Testing parameters:** USP specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	848098		
Description of Pack (Container closure system)	ALU-PVC Blister with unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	294B23	295B23	296B23
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	10-2023	10-2023	10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 8.6 gm **Dated:** 22-10-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Tablet PRAZ 1 mg (*Reg. # 028697)*

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Scilife Pharma (Pvt) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.**
	Change of Registration Holder (MA Holder) along with change of Manufacturing Site	
	From **M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **29-30 Sector 27 Korangi Industrial Area Karachi.**	**To** **M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837)** **Plot No.FD-57/58-A2, KCIP, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: AWG-RU4-JYAP Dated : 21-03-2024
	Details of fee submitted	PKR 30,000/-: 27-02-2024 (Slip # 80998135835)
	The proposed proprietary name / brand name	**Tablet PRAZ 0.5 mg (*Reg. # 028696)*** **Initial Registration:** 08-11-2002 **Change of brand name:** 03-06-2003 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Alprazolam ……. 0.5mg
	Pharmacotherapeutic Group of (API)	Benzodiazepines derivatives
	Reference to Finished product specifications	USP Specification

EVALUATION OF DATA

GMP status of the firm	**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 22-02-2023.
Evidence of approval of manufacturing facility	**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the grant of additional section **Tablet (Psychotropic) Section.**
Proposed Pack size	Proposed Pack size: 10's, 30's, 50's & 100's
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA approved formulation

For generic drugs (me-too status)	Azolam 1 mg tablet by Martin Dow
Name and address of API manufacturer.	CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 - 20067 PAULLO (MI) – Italy.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 12 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet PRAZ 0.5mg **Manufacturer:** Getz Pharma **Testing parameters:** USP specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	848098		
Description of Pack (Container closure system)	ALU-PVC Blister with unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	291B23	292B23	293B23
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	10-2023	10-2023	10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 8.6 gm **Dated:** 22-10-2023
Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

chromatograms, Raw data sheets, COA, summary data sheets etc.	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Tablet PRAZ 0.5 mg (*Reg. # 028696)*

Existing MAH & manufacturing site	**Proposed MAH & manufacturing site**
M/s Getz Pharma (Pvt.) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi.	M/s Scilife Pharma (Pvt) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.**
	Change of Registration Holder (MA Holder) along with change of Manufacturing Site	
	From **M/s Getz Pharma (Pvt.) Ltd. (DML # 000284)** **29-30 Sector 27 Korangi Industrial Area Karachi.**	**To** **M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837)** **Plot No.FD-57/58-A2, KCIP, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: TLH-7TT-A8LJ Dated : 20-03-2024
	Details of fee submitted	PKR 30,000/-: 27-02-2024 (Slip # 44753996400)
	The proposed proprietary name / brand name	**Tablet PRAZ 0.25 mg (*Reg. # 028695)*** **Initial Registration:** 08-11-2002 **Change of brand name:** 03-06-2003 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Alprazolam ……. 0.25mg
	Pharmacotherapeutic Group of (API)	Benzodiazepines derivatives
	Reference to Finished product specifications	USP Specification

EVALUATION OF DATA

GMP status of the firm	**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 22-02-2023.
Evidence of approval of manufacturing facility	**M/s Scilife Pharma (Pvt) Ltd. (DML # 000837)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the grant of additional section **Tablet (Psychotropic) Section.**

Proposed Pack size	Proposed Pack size: 10's, 30's, 50's & 100's
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA approved formulation
For generic drugs (me-too status)	Azolam 1 mg tablet by Martin Dow
Name and address of API manufacturer.	CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 - 20067 PAULLO (MI) – Italy.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 12 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet PRAZ 0.25mg **Manufacturer:** Getz Pharma **Testing parameters:** USP specification **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	848098		
Description of Pack (Container closure system)	ALU-PVC Blister with unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	288B23	289B23	290B23
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	10-2023	10-2023	10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 8.6 gm **Dated:** 22-10-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by DD-PE&R:	
Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: - **Tablet PRAZ 0.25 mg (*Reg. # 028695)*** **Existing MAH & manufacturing site**: M/s Getz Pharma (Pvt.) Ltd (DML # 000284) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi. **Proposed MAH & manufacturing site**: M/s Scilife Pharma (Pvt) Ltd. (DML # 000837) Plot No.FD-57/58-A2, KCIP, Karachi.	

Case No. 13: Change of Registration Holder (MA Holder) <u>along with change in manufacturing site.</u>

22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novartis Pharma (Pakistan) Limited (DML # 000003)** **C-21, S.I.T.E AREA, KARACHI**
	Change of Registration Holder (MA Holder)	
	From **M/s. Novartis (Pakistan) Private Limited (DML # 000193)** **15- west Wharf, Dockyard Road, Karachi.**	**To** **M/s Novartis Pharma (Pakistan) Limited (DML # 000003)** **C-21, S.I.T.E AREA, KARACHI**
	Along with change of manufacturing site	
	From (contract manufacturing) **M/s Haleon Pakistan (DML # 000010)** **Petaro Road Jamshoro.**	**To (self-manufacturing)** **M/s Novartis Pharma (Pakistan) Limited (DML # 000003)** **C-21, S.I.T.E AREA, KARACHI**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. YXJ-2DS-J6BP dated 18-03-2024
	Details of fee submitted	PKR 30,000/-: dated: 09-01-2024 (Invoice # 12246488033)
	The proposed proprietary name / brand name	**Tablet Voltral 50 mg *(Reg. # 021525)***
		Initial Registration: 20th May 1998

		Change in name of registration holder: *(From Sandoz to Novartis)* 23rd June 2007
		Contract Manufacturing: 13th February 2020
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet contains: Diclofenac Sodium……..…….…….……50 mg
	Pharmaceutical form of applied drug	Enteric coated tablet
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	20's & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Doloflam by pulse Pharmaceuticals
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **18th August 2025**
	Name and address of API manufacturer.	M/s Amoli Organics Pvt. Ltd. Plot # 322/4, 40 SHED Area GIDC VAPI, VALSAD Gujarat India. **GMP valid till 03-03-2026**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5% RH for 66 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Voltral 50 mg Tablet **Manufacturer:** Haleon Petaro Road Jomshoro **Testing Parameters:** BP Specifications **Comparative Dissolution Profile**

		Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Amoli Organics Pvt. Ltd. Plot # 322/4, 40 SHED Area GIDC VAPI, VALSAD Gujarat India.		
API Lot No.			
Description of Pack (Container closure system)	ALU-PVC Blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**BAD472**	**BAD482**	**BAD490**
Batch Size	1184210 Tablets	1184210 Tablets	1184210 Tablets
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	15-08-2023	15-08-2023	15-08-2023
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 700 kg **Dated:** 13-06-2023
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).

Section	**Observations**	**Reply of the firm**
1.3.4	• Contract termination letter with previously approved manufacturer by the MA holder.	submitted

	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI**.	Capacity assessment inspection is not yet conducted.
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change in source
3.2.P.3	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted
3.2.P.8	• Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Tablet Voltral 50 mg *(Reg. # 021525)*

Existing MAH	Proposed MAH & manufacturing site
M/s. Novartis (Pakistan) Private Limited (DML # 000193) 15- west Wharf, Dockyard Road, Karachi. (contract manufacturing) M/s Haleon Pakistan (DML # 000010) Petaro Road Jamshoro.	M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI

23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI**
	Change of Registration Holder (MA Holder)	
	From **M/s. Novartis (Pakistan) Private Limited (DML # 000193)** **15- west Wharf, Dockyard Road, Karachi.**	**To** **M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI**
	Along with change of manufacturing site	
	From (contract manufacturing) **M/s Haleon Pakistan (DML # 000010)** **Petaro Road Jamshoro.**	**To (self-manufacturing)** **M/s Novartis Pharma (Pakistan) Limited (DML # 000003)** **C-21, S.I.T.E AREA, KARACHI**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Track ID: E4R-RB1-MDPD dated 24-04-2024
	Details of fee submitted	PKR 30,000/-: dated: 09-01-2024 (Invoice # 61250167)
	The proposed proprietary name / brand name	**Voltral 100 mg SR Tablets *(Reg. # 021526)***
		Initial Registration: 20th May 1998
		Change in name of registration holder: *(From Sandoz to Novartis)* 23rd June 2007
		Contract Manufacturing: 13th February 2020
		Renewal Status: Valid

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified release tablet contains: Diclofenac Sodium……..……..……..…100 mg
	Pharmaceutical form of applied drug	Enteric coated tablet
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Australia approved formulation
	For generic drugs (me-too status)	Voveron Pharma by fynk pharma
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **18th August 2025**
	Name and address of API manufacturer.	M/s Amoli Organics Pvt. Ltd. Plot # 322/4, 40 SHED Area GIDC VAPI, VALSAD Gujarat India. **GMP valid till 03-03-2026**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5% RH for 66 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Voltral SR mg Tablet **Manufacturer:** Haleon Petaro Road Jomshoro **Testing Parameters:** BP Specifications **Comparative Dissolution Profile** Comparative dissolution profiles were provided, showing similarity between the manufacturer's product and the reference product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Amoli Organics Pvt. Ltd. Plot # 322/4, 40 SHED Area GIDC VAPI, VALSAD Gujarat India.		
API Lot No.			
Description of Pack (Container closure system)	ALU-PVC Blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**BAD593**	**BAD594**	**BAD595**
Batch Size	55 Packs	55 Packs	55 Packs
Manufacturing Date	09-2023	09-2023	09-2023
Date of Initiation	28-09-2023	28-09-2023	28-09-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 700 kg **Dated:** 13-06-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).

Section	**Observations**	**Reply of the firm**
1.3.4	• Contract termination letter with previously approved manufacturer by the MA holder.	submitted
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI**.	Capacity assessment inspection is not yet conducted.
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change in source

3.2.P.3	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted
3.2.P.8	• Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change in manufacturing site as under: -

Voltral 100 mg SR Tablets *(Reg. # 021526)*

Existing MAH	Proposed MAH & manufacturing site
M/s. Novartis (Pakistan) Private Limited (DML # 000193) 15- west Wharf, Dockyard Road, Karachi. (contract manufacturing) M/s Haleon Pakistan (DML # 000010) Petaro Road Jamshoro.	M/s Novartis Pharma (Pakistan) Limited (DML # 000003) C-21, S.I.T.E AREA, KARACHI

Case No. 14: Change in manufacturing site of Rocephin.

24.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Change of Manufacturing Site	
	From (Import) Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland	**To (contract manufacturing) M/s GlaxoSmithKline Pakistan Limited (DML # 000248) Plot # 5 Sector 21 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track BS7-UL7-2Y6V Dated : 18-03-2024
	Details of fee submitted	PKR 75,000/-: 05-03-2024 (Slip # 6146240266)
	The proposed proprietary name / brand name	Rocephin 500mg I.V Injection ***(Reg. # 008435)*** **Initial Registration:** 28-05-1985 **Transfer of Registration:** 17-12-1997 **Transfer of Registration:** 29-06-2010 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: (Powder for reconstitution) Ceftriaxone (as sodium) ……. 500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's Specification
EVALUATION OF DATA		
GMP status of the firm		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 26-06-2023.
Evidence of approval of manufacturing facility		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the renewal of DML including **Dry powder Injection vials (Cephalosporin).**
Proposed Pack size		1's

Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA approved formulation
For generic drugs (me-too status)	Locally registered in Pakistan
Name and address of API manufacturer.	Manufacturing facility address for Ceftriaxone Sodium Sterile ACS DOBFAR S.p.A. 2: Addetta Site Viale Addetta, 2a/12 – 3/5 20067 Tribiano Milano – Italy
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocephin 500 mg IV injection **Manufacturer:** Martin Dow Pharma **Testing parameters:** Innovator specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	848098		
Description of Pack (Container closure system)	Type I clear glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRIAL -02	TRIAL -08	TRIAL -10
Batch Size	1200 Vials	1200 vials	1200 vials
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	16-08-2023	16-08-2023	16-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 19.5 kg **Dated:** 27-07-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Section	Observations	
1.3.4	• Please submit details of technology transfer and method of evaluation and selection of proposed manufacturing site for manufacturing of Rocephin.	Submitted
	• Please submit **"No Objection Certificate"** issued by **Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland** for allowing local manufacture of brand name "**Rocephin**".	Submitted
	• Please submit Section approval letter of manufacturing facility of GlaxoSmithKline for injection cephalosporin which has been issued by Licensing Division DRAP after approval in minutes of Central Licensing Board.	Submitted
	• Please submit colored copy of revised label of Rocephin for the primary and secondary packaging and details of change in logo if any?	Submitted
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s GlaxoSmithKline Pakistan Limited (DML # 000248).**	GMP inspection report submitted
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change
3.2.P.3	• Please submit the details of implementation of technology transfer by **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)**.	
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	SUBMITTED
3.2.P.8	• Please submit source of diluent, its registration letter, and stability data after reconstitution.	
	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**	Submitted

Decision: Registration Board acceded to the request of the applicant for change in manufacturing site from import to local manufacturing as under: -		
Applicant name / Marketing Authorization Holder		**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
Drug Product details		**Rocephin 500mg I.V Injection (*Reg. # 008435)*** **Innovator's Specification**
From (Import) Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland		**Local Manufacturing site – contract Basis** M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Change of Manufacturing Site	
	From (Import) Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland	**To (contract manufacturing) M/s GlaxoSmithKline Pakistan Limited (DML # 000248) Plot # 5 Sector 21 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track 8JZ-DX8-8UZ2 Dated : 18-03-2024
	Details of fee submitted	PKR 75,000/-: 05-03-2024 (Slip # 6146240266)
	The proposed proprietary name / brand name	**Rocephin 500mg I.M Injection (*Reg. # 008435)*** **Initial Registration:** 28-05-1985 **Transfer of Registration:** 17-12-1997 **Transfer of Registration:** 29-06-2010 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: (Powder for reconstitution) Ceftriaxone (as sodium) ……. 500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's Specification
EVALUATION OF DATA		
GMP status of the firm		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 26-06-2023.
Evidence of approval of manufacturing facility		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the renewal of DML including **Dry powder Injection vials (Cephalosporin).**
Proposed Pack size		1's
Proposed unit price		As per SRO
The status in reference regulatory authorities		USFDA approved formulation
For generic drugs (me-too status)		Locally registered in Pakistan

Name and address of API manufacturer.	Manufacturing facility address for Ceftriaxone Sodium Sterile ACS DOBFAR S.p.A. 2: Addetta Site Viale Addetta, 2a/12 – 3/5 20067 Tribiano Milano – Italy
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocephin 500 mg IM injection **Manufacturer:** Martin Dow Pharma **Testing parameters:** Innovator specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	848098		
Description of Pack (Container closure system)	Type I clear glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRIAL -01	TRIAL -07	TRIAL -09
Batch Size	1200 Vials	1200 vials	1200 vials
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	16-08-2023	16-08-2023	16-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 19.5 kg **Dated:** 27-07-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Section	Observations	
1.3.4	• Please submit details of technology transfer and method of evaluation and selection of proposed manufacturing site for manufacturing of Rocephin.	Submitted
	• Please submit **"No Objection Certificate"** issued by **Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland** for allowing local manufacture of brand name "**Rocephin**".	Submitted
	• Please submit Section approval letter of manufacturing facility of GlaxoSmithKline for injection cephalosporin which has been issued by Licensing Division DRAP after approval in minutes of Central Licensing Board.	Submitted
	• Please submit colored copy of revised label of Rocephin for the primary and secondary packaging and details of change in logo if any?	Submitted
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s GlaxoSmithKline Pakistan Limited (DML # 000248).**	GMP inspection report submitted
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change
3.2.P.3	• Please submit the details of implementation of technology transfer by **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)**.	
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	SUBMITTED
3.2.P.8	• Please submit source of diluent, its registration letter, and stability data after reconstitution.	
	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**	Submitted

Decision: Registration Board acceded to the request of the applicant for change in manufacturing site from import to local manufacturing as under: -

	Applicant name / Marketing Authorization Holder	**M/s Martin Dow Limited. (DML # 000267)** **Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Drug Product details	**Rocephin 500mg I.M Injection (*Reg. # 008435)*** **Innovator's Specification**
	From (Import) Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland	**Local Manufacturing site – contract Basis** M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267)** **Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Change of Manufacturing Site	
	From (Import) **Hoffman La Roche** **Grenzacherstrasse 124, 4058 Basel, Switzerland**	**To (contract manufacturing)** **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** **Plot # 5 Sector 21 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track N95-B4W-ELNT Dated : 18-03-2024
	Details of fee submitted	PKR 75,000/-: 05-03-2024 (Slip # 1310335241)
	The proposed proprietary name / brand name	**Rocephin 1GM I.M Injection (*Reg. # 008436)*** **Initial Registration:** 28-05-1985 **Transfer of Registration:** 17-12-1997 **Transfer of Registration:** 29-06-2010 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: (Powder for reconstitution) Ceftriaxone (as sodium) ……. 1 GM
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's Specification
EVALUATION OF DATA		
GMP status of the firm		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 26-06-2023.
Evidence of approval of manufacturing facility		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the renewal of DML including **Dry powder Injection vials (Cephalosporin).**
Proposed Pack size		1's
Proposed unit price		As per SRO
The status in reference regulatory authorities		USFDA approved formulation
For generic drugs (me-too status)		Locally registered in Pakistan
Name and address of API manufacturer.		Manufacturing facility address for Ceftriaxone Sodium Sterile ACS DOBFAR S.p.A. 2: Addetta Site Viale Addetta, 2a/12 – 3/5 20067 Tribiano Milano – Italy

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocephin 1 GM IM injection **Manufacturer:** Martin Dow Pharma **Testing parameters:** Innovator specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	848098		
Description of Pack (Container closure system)	Type I clear glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRIAL -03	TRIAL -05	TRIAL -11
Batch Size	312 Vials	312 vials	312 vials
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	16-08-2023	16-08-2023	16-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 19.5 kg **Dated:** 27-07-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by DD-PE&R:	

Section	Observations	
1.3.4	• Please submit details of technology transfer and method of evaluation and selection of proposed manufacturing site for manufacturing of Rocephin.	Submitted
	• Please submit **"No Objection Certificate"** issued by **Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland** for allowing local manufacture of brand name "**Rocephin**".	Submitted
	• Please submit Section approval letter of manufacturing facility of GlaxoSmithKline for injection cephalosporin which has been issued by Licensing Division DRAP after approval in minutes of Central Licensing Board.	Submitted
	• Please submit colored copy of revised label of Rocephin for the primary and secondary packaging and details of change in logo if any?	Submitted
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s GlaxoSmithKline Pakistan Limited (DML # 000248).**	GMP inspection report submitted
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change
3.2.P.3	• Please submit the details of implementation of technology transfer by **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)**.	
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	SUBMITTED
3.2.P.8	• Please submit source of diluent, its registration letter, and stability data after reconstitution.	
	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**	Submitted

Decision: Registration Board acceded to the request of the applicant for change in manufacturing site from import to local manufacturing as under: -

Applicant name / Marketing Authorization Holder	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
Drug Product details	**Rocephin 1GM I.M Injection (*Reg. # 008436)*** **Innovator's Specification**

	From (Import) Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland	**Local Manufacturing site – contract Basis** M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
27.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267)** **Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Change of Manufacturing Site	
	From (Import) **Hoffman La Roche** **Grenzacherstrasse 124, 4058 Basel, Switzerland**	**To (contract manufacturing)** **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** **Plot # 5 Sector 21 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track N95-B4W-ELNT Dated : 18-03-2024
	Details of fee submitted	PKR 75,000/-: 05-03-2024 (Slip # 1310335241)
	The proposed proprietary name / brand name	**Rocephin 1GM I.V Injection (*Reg. # 007014)*** **Initial Registration:** 18-04-1985 **Transfer of Registration:** 17-12-1997 **Transfer of Registration:** 29-06-2010 **Renewal Status:** Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: (Powder for reconstitution) Ceftriaxone (as sodium) ……. 1 GM
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Innovator's Specification
EVALUATION OF DATA		
GMP status of the firm		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 26-06-2023.
Evidence of approval of manufacturing facility		**M/s GlaxoSmithKline Pakistan Limited (DML # 000248)** Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the renewal of DML including **Dry powder Injection vials (Cephalosporin).**
Proposed Pack size		1's
Proposed unit price		As per SRO
The status in reference regulatory authorities		USFDA approved formulation
For generic drugs (me-too status)		Locally registered in Pakistan
Name and address of API manufacturer.		Manufacturing facility address for Ceftriaxone Sodium Sterile ACS DOBFAR S.p.A. 2: Addetta Site Viale Addetta, 2a/12 – 3/5 20067 Tribiano Milano – Italy
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:		Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance		Firm has submitted stability study data of 3 batches of drug

(Conditions & duration of Stability studies)	substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocephin 1 GM IM injection **Manufacturer:** Martin Dow Pharma **Testing parameters:** Innovator specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	848098		
Description of Pack (Container closure system)	Type I clear glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRIAL -03	TRIAL -05	TRIAL -11
Batch Size	312 Vials	312 vials	312 vials
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	16-08-2023	16-08-2023	16-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 19.5 kg **Dated:** 27-07-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Section	Observations	
1.3.4	• Please submit details of technology transfer and method of evaluation and selection of proposed manufacturing site for manufacturing of Rocephin.	Submitted

	• Please submit **"No Objection Certificate"** issued by **Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland** for allowing local manufacture of brand name "**Rocephin**".	Submitted
	• Please submit Section approval letter of manufacturing facility of GlaxoSmithKline for injection cephalosporin which has been issued by Licensing Division DRAP after approval in minutes of Central Licensing Board.	Submitted
	• Please submit colored copy of revised label of Rocephin for the primary and secondary packaging and details of change in logo if any?	Submitted
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s GlaxoSmithKline Pakistan Limited (DML # 000248).**	GMP inspection report submitted
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	No change
3.2.P.3	• Please submit the details of implementation of technology transfer by **M/s GlaxoSmithKline Pakistan Limited (DML # 000248)**.	
	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	SUBMITTED
3.2.P.8	• Please submit source of diluent, its registration letter, and stability data after reconstitution.	
	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**	Submitted

Decision: Registration Board acceded to the request of the applicant for change in manufacturing site from import to local manufacturing as under: -

Applicant name / Marketing Authorization Holder	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
Drug Product details	**Rocephin 1GM I.V Injection (*Reg. # 007014)* Innovator's Specification**
From (Import)	**Local Manufacturing site – contract Basis**
Hoffman La Roche Grenzacherstrasse 124, 4058 Basel, Switzerland	M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Case No. 15: Change in manufacturing site of Ciproxin Infusion.

M/s OBS Pharma (Pvt) Ltd *(special purpose vehicle for AGP Pharma Group Companies)* has acquired certain assets of M/s Bayer Pakistan (Private) Limited (DML # 000243) by an asset purchase agreement including Ciproxin Infusion 0.2 gm.
Accordingly, the change in title of the firm from **M/s Bayer Pakistan (Private) Limited (DML # 000243) 108 Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan** to **M/s OBS Pharma (Pvt.) Ltd. (DML # 000243), 108 Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan** has been approved for the Ciproxin Infusion in 114th meeting of post registration variation committee.
M/s OBS Pharma (Private) Limited has now submitted an application for change in manufacturing site of drug Product Ciproxin Infusion *(Reg. # 109732)* from Finished Import (Bulk Import and local Repack) to **Local manufacturing on contract basis** from M/s Surge Laboratories (Pvt.) Ltd (DML # 000484)

28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s OBS Pharma (Pvt.) Ltd. (DML # 000243)** ***(formerly M/s Bayer Pakistan (Private)Limited)*** **108 Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan.**
	Change of Manufacturing Site	
	From (Contract basis) ***(bulk manufacturing and primary packaging)*** **Bayer AG, Leverkusen, Kaiser-Wilhelm-Allee Leverkusen Germany.** ***(Secondary packaging Quality Control & Batch Release Site)*** **M/s Novartis Pharma (DML # 000003) C-21, S.I.T.E, Karachi.**	**Local Manufacturing To (Contract basis)** **M/s Surge Laboratories (Pvt.) Ltd. (DML # 000484) 10-Km Faisalabad Road, Bikhi, District Sheikhupura, Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track I0044. XMM-A1R-AAB5: 21-05-2024
	Details of fee submitted	PKR 30,000/-: 13-11-2023 (Slip # 9734949696)
	The proposed proprietary name / brand name	**Ciproxin solution 0.2 % for infusion *(Reg. # 109732)***
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Ciprofloxacin Lactate equivalent to Ciprofloxacin ……. 200 mg
	Pharmacotherapeutic Group of (API)	Quinolone antibacterial
	Reference to Finished product specifications	USP Specification

EVALUATION OF DATA	
GMP status of the firm	**M/s Surge Laboratories (Pvt.) Ltd. (DML # 000484)** Firm has submitted copy of GMP certificate of the firm based on inspection dated 25-08-2022.
Evidence of approval of manufacturing facility	**M/s Surge Laboratories (Pvt.) Ltd. (DML # 000484)** Central Licensing Board in its 284th meeting held on 16th December 2021 approved the renewal of DML # 000484 Including Liquid Injectable (including blow fill seal area)
Proposed Pack size	Type I glass 100 ml vial
Proposed unit price	As per SRO
The status in reference regulatory authorities	MHRA approved formulation

For generic drugs (me-too status)	Cipesta 200mg/100ml Infusion by Getz Pharma
Name and address of API manufacturer.	ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD. No.6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P. R. China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Ciproxin 200 mg / 100 ml infusion **Manufacturer:** Bayer Pakistan **Testing parameters:** USP specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	104-2209002		
Description of Pack (Container closure system)	100 ml clear colorless glass vial USP type-II with bromobutyl rubber stopper and aluminum flipoff-cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CPI-034	CPI-035	CPI-036
Batch Size	294 Vials	294 Vials	294 Vials
Manufacturing Date	May 2023	May 2023	May 2023
Date of Initiation	May 2023	May 2023	May 2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 08-12-2024
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 2 kg **Dated:** 06-03-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.3.4	• Please submit initial registration letter of Ciproxin Infusion, its trail and renewal status.	Submitted
	• Please submit details of asset purchase agreement regarding mode of technology transfer and method of evaluation and selection of proposed manufacturing site for manufacturing of Ciproxin infusion.	Submitted
	• Please submit **"No Objection Certificate"** issued by Bayer AG, Germany for allowing OBS to use brand name "**Ciproxin**" and undertake that all records and documentation, related to control of manufacture of **Ciproxin®** has been handed over to OBS	Divestment of Product Portfolio – Authorization Letter issued by Bayer AG, Germany attached
	• Please submit documented evidence that manufacturing facility of Surge fulfills the criteria and quality parameters as previous manufacturing site.	The GMP inspection report, issued by DRAP, provides documented evidence that Surge's manufacturing facility meets the same criteria and quality parameters as the previous manufacturing site. This report is attached as Annex 4. Additionally, the Export GMP certificates issued by the exporting countries are also included in Annex 4.
	• Please submit colored copy of revised label of ciproxin for the primary and secondary packaging and details of change in logo if any?	Submitted
	• Contract termination letter with previously approved manufacturer by the MA holder.	The OBS contract agreement with Novartis, which specifies the contract manufacturing of the Ciproxin tablet range only, is attached as Annex 6. Please note that after the divestment of the product portfolio from Bayer to OBS, we have not contracted Novartis for Ciproxin IV infusion, as evident from the attached contract. Ciproxin IV has not been imported and repacked at Novartis after the transfer of MAH to OBS.
	• Please submit the inspection report conducted within last three years for the purpose of capacity assessment of manufacturing facility of **M/s Surge Laboratories (Pvt.) Ltd. (DML # 000484)**.	Submitted
1.6.5	• Is source of API same for the existing and proposed manufacturing site?	Yes, we do possess the same source of API for both the proposed and existing manufacturing sites. Additionally, we have developed an alternative source, Goubang, for which stability data has been submitted.
	• Please justify that API supplier chosen by OBS has same impurity profile of API and bioequivalence to the API supplier of Bayer Germany.	The additional source, along with the primary source Bayer AG, is equivalent to Bayer AG, as the supplier Goubang is EDQM qualified. The CEP is attached as Annex 8.
3.2.P.3	• Please submit the details of implementation of technology transfer by Bayer Germany for the manufacturing of Ciproxin infusion.	The Product Development Report of Ciproxin Infusion by Bayer AG, which has been replicated in the development of the same product by Surge, is attached as Annex 9

	• Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site.	Submitted
3.2.P.8	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.**	Submitted

Decision: Registration Board acceded to the request of the applicant for change in manufacturing site from import to local manufacturing as under: -

Applicant name / Marketing Authorization Holder	**M/s OBS Pharma (Pvt.) Ltd. (DML # 000243)** ***(formerly M/s Bayer Pakistan (Private)Limited)*** **108 Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan.**
Drug Product details	**Ciproxin solution 0.2 % for infusion *(Reg. # 109732)*** **USP Specification**
From (Contract basis)	**Local Manufacturing (Contract basis)**
(bulk manufacturing and primary packaging) **Bayer AG, Leverkusen, Kaiser-Wilhelm-Allee Leverkusen Germany.**	**M/s Surge Laboratories (Pvt.) Ltd. (DML # 000484)** **10-Km Faisalabad Road, Bikhi, District Sheikhupura, Pakistan.**
(Secondary packaging Quality Control & Batch Release Site) **M/s Novartis Pharma (DML # 000003) C-21, S.I.T.E, Karachi.**	

Case No. 15: Delegation of Functions

Registration Board, in its 307th has authorized its Chairman certain functions, under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in order to facilitate timely disposal of various cases / post-registration variation cases/ contravention of various provisions of the Drugs Act, 1976. However, Post Registration Variation Section of PE&R Division is receiving applications for following and these functions are still not delegated to Chairman Registration Board:

i. Change of name & address of Product License Holder (Local)
ii. Change/Update in name & address of API/ Half-finished product manufacturer.
iii. Addition and or Replacement of manufacturing site of API.
iv. Change/ Update of Analytical Procedures of finished product in case of Pharmacopoeial methods.

If agreed, the above mentioned functions may also be delegated to Chairman Registration Board.

Decision:

Registration Board authorized its Chairman for above mentioned functions, under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in order to facilitate timely disposal of such cases.

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Semos Pharmaceuticals (Pvt.) Ltd, Plot No. 11, Sector 12-A, North Karachi Industrial Area, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents

Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-1/93-Lic dated 04-10-2019
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 20-12-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Heamgain Syrup Each 15ml contains: Ferric Ammonium Citrate B.P.....160mg Folic Acid USP.....0.5mg Cyanocobalamin USP.....7.5mcg Cupric Sulfate USP.....30mcg Manganese Sulfate USP.....30mcg In a caramel syrup flavour base	Purchase order from Somalia	Dy. No. 151(25.01.2024) Rs.30,000/-08.11.2023) Rs.45,000/-14.11.2023)

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Case No.02: Registration of Drug (s) of M/s Vetz Pharmaceutical (Pvt.) Ltd, Q-1, SITE, Kotri Sindh, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-8/2011-Lic dated 24-06-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 09-03-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Amo-Vetz Injection 50ml Each ml contains: Ammonium chloride.....20mg	Purchase order from Oman	Dy. No. 169/24(26.01.2024) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023)
2.	DS-Vetz Injection 100ml Each ml contains: Dichloro-acetic acid.....120mg Sodium gluconate USP.....250mg	Purchase order from Oman	Dy. No. 191/24(29.01.2024) Rs.30,000/- (11.08.2023) Rs.45,000/- (20.10.2023)

Decision:

Registration Board deliberated that the aforementioned formulations are neither available in Pakistan nor in RRAs, however, the said formulations do not require any special manufacturing

conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the products exclusively for Export Purpose only.

Case No.03: Registration of Drug (s) of M/s Swera Pharmaceuticals, Plot No. 27, Street No. S-4, Industrial area, Rawat, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-42/2011-Lic dated 16-09-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 30-06-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Roydol 225mg Tablet Each film coated tablet contains: Carisoprodol.....225mg	Purchase order from Oman **Available as 250mg & 350mg uncoated Tablet in FDA**	Dy. No. 152/24(26.01.2024) Rs.75,000/- (08.08.2023)

Decision:

Registration Board deferred the case for submission of clarification of applied strength i.e, 225 mg where as 250mg & 350mg strengths are available in USFDA.

Case No.04: Registration of Drug (s) of M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, Pharmaceuticals, Plot No. 27, Street No. S-4, Industrial area, Rawat, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-21/2015-Lic dated 01-21-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 03-04-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	L-Throx 100mcg Tablet Each uncoated tablet contains: Levothyroxine sodium USP.....100mcg	Purchase order from senegal	Dy. No. 194/24(20.02.2024) Rs.30,000/- (05.12.2023)

"The brand name "Thyrox" is already registered in name of M/s Pharmedic Laboratories for same formulation. However, the firm is requesting to grant them the Same name and submitted the Export Order from Senegal.

Decision: **Registration Board acceded to request of the firm for registration of above mentioned product for Export Purpose Only.**

Case No.05: **Registration of Drug (s) of M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, Pharmaceuticals, Plot No. 27, Street No. S-4, Industrial area, Rawat, Contract manufacturing by M/s Wallace Pharma Evolutions, Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore, for export purposes only.**

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Inspection report for cGMP dated 13-04-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 9-12-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Zotas DS 4.5gm Injectio Each vial contains: Piperacillin as sodium USP.....4000mg Tazobactam as sodium USP.....500mg	Purchase order from senegal	Dy. No. 195/24(20.02.2024) Rs.30,000/- (05.12.2023) Rs.30,000/- (02.01.2024) Fee for standardization
2.	Mynomin 1000mg Injection Each vial contains: Meropenem as trihydrate.....1000mg (Blended with sodium Bicarbonate)	Purchase order from senegal	Dy. No. 196/24(20.02.2024) Rs.30,000/- (05.12.2023)

The brand name "Azotas" is already registered in name of M/s Tas Pharma, Islamabad for Azithromycin 250mg Capsule. However, the firm is requesting to grant them above name and submitted the Export Order from Senegal.

The brand name "Gynomin" is already registered in name of M/s Shaigan Pharma, Rawalpindi for Mrthyloestrenolon + Methylestradiol combination Tablet. However, the firm is requesting to grant them above name and submitted the Export Order from Senegal.

Decision: **Registration Board acceded to request of the firm for registration of above mentioned products for Export Purpose Only.**

Case No.06: **Registration of Drug (s) of M/s Winthrox Laboratories (Pvt.) Ltd, Plot No. K-219/A, Phase-II, SITE Super Highway, Karachi, for export purposes only.**

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-38/2011-Lic dated 08-06-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 31-01-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Kymoze Tablet Each enteric coated tablet contains: Bromelain.....20,000IU (50mg)+ Trypsin.....2,500IU (1mg)	Purchase order from Myanmar	Dy. No. 201/24(22.02.2024) Rs.30,000/- (23.12.2023) Rs.45,000/- (19.01.2023)

The brand name "Kymoze" is already registered in name of M/s ISIS Pharmaceutical, Karachi. However, the firm has submitted a copy of NOC from M/s ISIS Pharmaceuticals for which ISIS Pharmaceuticals submitted that they had not given any NOC.

Decision:

Registration Board deferred the case for submission of more brand names which do not resemble with already registered drugs.

Case No.07: Registration of Drug (s) of M/s Nabi Qasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-20/85-Lic dated 27-04-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 22-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Glempa-MXR 5/850mg Tablets Each film coated tablet contains: Empagliflozin …….....……..5mg (as Immediate Release Coating) Metformin Hydrochloride.....…850mg (as Extended Release Core)	Purchase order from Tanzania	Dy. No. 223/24(23.02.2024) Rs. 75,000/- (17.11.2023)
2.	Glempa-MXR12. 5/850mg Tablets Each film coated tablet contains: Empagliflozin …….....……12.5mg (as Immediate Release Coating) Metformin Hydrochloride.....…850mg (as Extended Release Core)	Purchase order from Tanzania	Dy. No. 224/24(23.02.2024) Rs. 75,000/- (17.11.2023)
3.	Vitroline Multical Plus Sachet Each sachet contains: Calcium Glycerophosphate.....373.3mg Calcium carbonate.....156.7mg Calcium D-Pantothenate.....15.0mg Pyridoxine HCl (Vitamin B6).....10.0mg Thiamine HCl (Vitamin B1).....15.0mg Ascorbic Acid (Vitamin C).....100.0mg Riboflavin (Vitamin B2).....15.0mg Nicotinamide.....50.0mg	Purchase order from kyrgyzstan	Dy. No. 377/24(13.03.2024) Rs. 75,000/- (20.12.2023)

Decision:

Registration Board deliberated that the aforementioned formulations are neither available in Pakistan nor in RRAs, however, the said formulations do not require any special manufacturing

conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the products exclusively for Export Purpose only.

Case No.08: Registration of Drug (s) of M/s Surge Laboratories (Pvt.) Ltd, 10-Km, faisal Abad Road, Bikhi District, Sheikhupura, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-18/95-Lic dated 11-01-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 25-08-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Lidocaine HCl 1% 3.5ml Injection Each 3.5ml plastic ampoule contains: Lidocaine HCl USP …….....35mg	Purchase order from Tanzania	Dy. No. 225/24(23.02.2024) Rs. 75,000/- (07.12.2023)

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Case No.09: Registration of Drug (s) of M/s Sami Pharmaceuticals, (Pvt.) Ltd, F-95, Off Hub River Road, S.I.T.E. Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-9/2007-Lic dated 22-06-2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 23-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Provas Trio Tablets Each film coated tablet contains: Paracetamol.....250mg Ibuprofen.....200mg Caffeine.....50mg	Purchase order from Afghanistan	Dy. No. 344/24(27.02.2024) Rs. 75,000/- (24.10.2023)

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing

conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Case No.10: Registration of Drug (s) of M/s MBL Pharma, Plot No. B-77/A, Hub Industrial Trading Estate, Balochistan, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Inspection report renewal of DML dated 04-07-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 10-03-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Monti Tablet 4mg Each Chewable tablet contains: Montelukast as sodium.....4mg	Aerokast tablet by M/s Barrett	Dy. No. 381/24(13.03.2024) Rs. 30,000/- (13.06.2023)

Remarks:

This brand name is already registered in name of M/s Lisko Pharma Karachi. However, the firm submitted that same brand name with different strength 10mg is registered in Sri Lanka and now they are requesting for 4mg with same brand name.

Decision: Registration Board acceded to request of the firm for registration of above mentioned product for Export Purpose to Sri Lanka Only.

Deferred case 110-PRVC

Case No.12: Registration of Drug (s) of M/s Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E. Landhi Karachi, export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 396-414/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page- 403 /C). Approval of relevant section verified from letter No. F 2-1/2003-Lic dated 21-06-2021 (Page 405/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 02-02-2023 (Page 406/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 407-415/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Mupin Ointment Each gram contains: Mupirocin.....20mg (2% w/w)	Baetroban Ointment by GSK	Dy. No. 1501/10 (19.12.2023) Rs.30,000/- (23.11.2023)

Decision of 110th PRVC:

"*The Chairman Registration Board on recommendation of Committee considered the case and acceded to request of the firm for registration of product at sr. no. 65 for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs).*"

Updated Status

The brand name "Mupir" is already registered in name of M/s Valor Pharma, Lahore for same formulation. However, the firm is requesting to grant them above name and submitted that their above mentioned product had already been registered with same brand name in FDA Philippines. The firm has submitted the copy of Certificate of Listing of Identical Drug Product.

Decision: Registration Board acceded to request of the firm for registration of above mentioned products for Export Purpose to Philippines Only.

Deferred case 116-PRVC

Case No.13: Registration of Drug (s) of M/s Nabi Qasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 259-357/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-268/C). Approval of relevant section verified from letter No. F 2-20/85-Lic dated 27-04-2020 (Page 267/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 22-05-2023 (Page 269/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 270-258/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Amlotan Duo Tablet (5/160mg) Each film coated tablet contains: Amlodipine besylate USP eq. to Amlodipine ….....5mg Valsartan USP….....160mg	Valam tablet 5mg/160mg by M/s CCL	Dy. No. 231/24 (23.02.2024) Rs.30,000/- (30.01.2024)
2.	Amlotan Trio Tablet (5mg/160mg/12.5mg) Each film coated tablet contains: Amlodipine besylate USP eq. To Amlodipine …….....5mg Valsartan USP….....…160mg Hydrochlorothiazide USP..….....12.5mg	Valam-H tablet 5mg/160mg/12.5mg by M/s CCL	Dy. No. 235/24 (23.02.2024) Rs.30,000/- (30.01.2024)

Decision of 116th PRVC:

"The Chairman Registration Board on recommendation of Committee decided as follows:

- *Acceded to the request of the firm for registration of products at sr. no. 28 & 32 for Export Purpose Only subject to submission of more brand names which do not resemble to already registered products."*

Updated Status

The firm has stated that the above mentioned brand names are required by the importing country and provided export order.

Decision:

Registration Board acceded to request of the firm for registration of above mentioned products for Export Purpose Only. The firm will change the brand name in case of any representation of already registered product holder for resemblance of brand name.

CASE OF 109-PRVC

Case No.14: Registration of Drug (s) of M/s Sami Pharmaceuticals (Pvt.) Ltd, F-95, Off Hub River Road, S.I.T.E. Karachi, export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 875-897/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page- 881/C). Approval of relevant section verified from letter No. F 2-9/2007-Lic dated 22-06-2018 (Page 882/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 23-05-2023 (Page 883-886 /C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 887-898 /C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Omesam Insta 40mg Sachet Each Sachet contains: Omeprazole.....40mg Sodium bicarbonate.....1680mg	Risek Insta Sachet by M/s Getz	Dy. No. 1432/10 (01.12.2023) Rs.30,000/- (31.10.2023)
2.	Omesam Insta 20mg Sachet Each Sachet contains: Omeprazole.....20mg Sodium bicarbonate.....1680mg	Risek Insta Sachet by M/s Getz	Dy. No. 1433/10 (01.12.2023) Rs.30,000/- (07.11.2023)

Decision of 109th PRVC:

"The Chairman Registration Board on recommendation of Committee considered the case and decided as follows:

- *Acceded to request of the firm for registration of products at sr. no. 99-100 for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs)."*

Updated Status

The firm has stated that the above mentioned Products already granted the Registration of OMESAM brand name with the name of OMESAM 40mg Infusion bearing registration No. 013496-EX (Copy attached) the firm has further requested that to issue us registration of our line extension product as subjected to accomplish the export order as soon as possible.

Decision: Registration Board acceded to request of the firm for registration of above mentioned products for Export Purpose to Sri Lanka Only.

CASE OF 113-PRVC

Case No.15: Registration of Drug (s) of M/s Macter International Ltd, F-216, S.I.T.E. Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 956-1130/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page-963-A/C). Approval of relevant section verified from letter No. F 2-13/95 dated10-12-2019 (Page 963-B/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 08-08-2022 (Page 963-C/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 963-1130/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
2.	Dexlan 60 mg Capsule Each capsule contains: Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole….....60mg **Source of Pellets: M/s Vision Pharma Islamabad**	Dextop Capsules 60mg by M/s Searle	Dy. No. 112/24 (23.01.2024) Rs.30,000/- (29.12.2023)
3.	Dexlan 30 mg Capsule Each capsule contains: Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole…..30mg **Source of Pellets: M/s Vision Pharma Islamabad**	Dextop Capsules 30mg by M/s Searle	Dy. No. 113/24 (23.01.2024) Rs.30,000/- (29.12.2023)

Decision of 113th PRVC: *"The Chairman Registration Board on recommendation of Committee considered the case and decided as follows:*

- *Acceded to request of the firm for registration of products at sr. no. 133-134 for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs) and source of pellets along with applicable fee."*

UPDATED STATUS

The said brand name is alreay registered in name of M/s Crystolite. Now, the firm has submitted source of pellets as M/s Vision Pharma and submitted the copy of no objection certificate (NOC) from Yashfeen Pharma Afghanistan for brand name i.e. Dexlan for getting registration on exclusive for Export for Afghanistan which is already registered trade mark of Yashfeen Pharmain Afghanistan (copy of trade mark registration provided).

Decision:

Registration Board deferred the case for submission of more brand names which do not resemble with already registered drugs OR NOC for export with said brand name from existing brand name holder.

CASE OF 119-PRVC

Case No.16: Registration of Drug (s) of M/s Genix pharma, 44-45 B, Korangi Creek Road, Karachi, for export purposes only.

Following product of M/s Genix Pharma was referred to RB in 119th PRVC as per following details:

Name of Manufacturer & Fee Details	Brand Name & Composition	Generic/RRA Status	Decision of 119th PRVC
M/s Genix pharma, 44-45 B Korangi Creek Road, Karachi License Number: **000351** Fee Paid: 75000.0 Challan No: 78205444637	**Respicare-F** Each Film Coated Tablet Contains: Montelukast Sodium eq. to Montelukast ..... 10mg Fexofenadine HCl……120mg	**Not Available** Purchase Order from Sri Lanka	*Referred to Registration Board as no RRA or Me-Too is available.*

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Case No. 17: Change of Brand Name

The following applications have been submitted by the different firms for the change of brand names of their registered drugs and submitted the documents as per SOP as mentioned below; -

Sr.#	Documents Required as per SOP.
a.	Application with required fee as per relevant SRO.
b.	Copy of registration letter and last renewal status.
c.	Justification for proposed change.
d.	Information regarding previous change of brand name since registration of drug.
e.	Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured.
f.	An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance /similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
g.	Undertaking that provided information/ documents are correct.

The details of firms and products are as follows:

Sr. #	Reg. No.	Name of Brand Name with composition	Proposed Brand Names	Date of Initial Reg. & Date of Renewal	Justification / Remarks/ Deficiency (if any)
M/s Indus Pharma (Pvt.) Ltd, Plot No. 26-27, 63-67, Sector-27, Korangi Industrial Area Karachi,					
1.	014660-EX	Ondansetron Injection 4mg/2ml 1ml solution for injection contains: Ondansetron as ondansetron hydrochloride dihydrate…...…….2mg	**Ondasetron 4mg/2ml.**	13.10.2023	**Justification:** As per marketing Importing country Fee Deposited of Rs.30000/- Dated 20.12.2023
The proposed brand name resembles with already registered brand name "Ondastron" of M/s Hiranis Pharmaceuticals. The firm has submitted the copy of letter issued by Ministry of Public Health & Population Supreme Board of Drugs & Medical Appliances, Yemen wherein the brand name Ondasetron is mentioned.					

Decision:

Registration Board deferred the case for submission of more brand names which do not resemble with already registered drugs OR NOC for export with said brand name from existing brand name holder.

Case. No. 18: Formulations Containing more than 100mg Tramadol: Case Meeting with Nigeria and the Islamic Republic of Pakistan.

A summary of case meeting with the Government of Nigeria and the Global Rapid Interdiction of Dangerous Substances (GRIDS) program was forwarded by Mr. Muhammad Arif Chaudhary, Additional Director, Control Drugs Division. The meeting was attended by following officers of the Authority;

1. Mr. Ahmad din Ansari, Director Division of controlled drugs DRAP Islamabad.
2. Mr. M. Arif Chaudhry, Additional Director Division of Controlled Drugs, DRAP Islamabad.

On the basis of proceedings of the meeting, above mentioned officers of the Authority have given following recommendations;

"It is submitted that in the light of discussion made during the meeting and stance of Nigerian Authorities, it is recommended that DRP may revise its policy for the already registered products containing "Tramadol" over 100mg and all the products registered with strength over 100mg may be withdrawn (even if for export purpose) after following due process of law. It is further recommended that policy regarding export of products containing synthetic opioid may be revised to make it in line with status of the material in importing country. The concerned authority of the importing country may also be taken on board for verification of import orders or request for registration of new strength as in case of Tramadol to avoid any sort of scam in future"

Registration Board in its 329th meeting while considering the matter, decided as follows:

"The Board referred the matter to Expert Working Group for the review of "Human Formulations of Pharmaceutical Drug Products" for review of formulations containing more than 100mg Tramadol in light

of report meeting with the Government of Nigeria and the Global Rapid Interdiction of Dangerous Substances and availability of sustained release formulations in reference regulatory authorities."

Following Working Group was constituted by the Board for review of Tramadol containing formulations:

i. Mr. Iftikhar A Chaudhary, Ex-Hospital Pharmacist, Lahore.
ii. Mr. Mehmood Baig, Deputy Director, DTL Quetta.
iii. Mr. M. Zubair Masood, Deputy Director (PR-II/EFD), PE&R DRAP, Islamabad.

The above mentioned Working Group recommended the following:

i. In future, only those Tramadol containing formulations may be registered (both for Local and Export Purpose) which are available in any of the RRAs as notified by Registration Board in its 275th meeting.
ii. Already registered Tramadol containing formulations which are not available in any of the above RRAs, may be withdrawn after following due process.
iii. The matter of inclusion of Tramadol in the list of Controlled Drugs is referred to the Division of Controlled Drugs, DRAP.
iv. The Division of Control Drugs DRAP may be requested to guide on the Export of such strengths not approved by any RRA.

The Board was further apprised by Export Facilitation Desk that Tramadol is available in following formulations in RRAs:

Sr. No.	Formulation	RRA
1.	50mg Capsule	MHRA
2.	100mg Capsule	SPAIN
3.	50mg Prolonged Release Capsule	MHRA
4.	100mg Prolonged Release Capsule	MHRA, USFDA
5.	150mg Prolonged Release Capsule	MHRA, USFDA
6.	200mg Prolonged Release Capsule	MHRA, USFDA
7.	50mg Effervescent Tablet, OD Tablet	MHRA, USFDA
8.	100mg Effervescent Tablet	ANSM FRANCE
9.	50mg Tablet	USFDA
10.	50mg Prolonged Release Tablet	MHRA
11.	75mg Prolonged Release Tablet	HEALTH CANADA
12.	100mg Prolonged Release Tablet	MHRA, USFDA
13.	150mg Prolonged Release Tablet	MHRA
14.	200mg Prolonged Release Tablet	MHRA, USFDA
15.	300mg Prolonged Release Tablet	MHRA, USFDA
16.	400mg Prolonged Release Tablet	MHRA
17.	Tramadol 37.5mg + Paracetamol 325mg Tablet	MHRA
18.	Tramadol 37.5mg + Paracetamol 325mg Effervescent Tablet	MHRA
19.	Tramadol 75mg + Paracetamol 650mg	MHRA
20.	50mg/ml Injection	MHRA
21.	10mg/ml Oral Solution	MHRA
22.	100mg/ml Oral Drops	MHRA

Decision:

Registration Board deliberated the matter in detail and decided as follows:

i. Only those Tramadol containing formulations shall be registered (both for Local and Export Purpose Only) which are available in any of the RRAs as notified by Registration Board in its 275th meeting. The matter of export of those strtengths not approved/available in any RRA will be referred to the division of Controlled Drugs, DRAP for opinion.

ii. Registration of Tramadol containing formulations for Export Purpose Only shall be granted after submission of Export Order endorsed by Regulatory Authority of country of import.

iii. Issue an Advisory to all registration holders of Tramadol containing formulations which are not available in any of the above RRAs to standardize formulation of such registered drugs as per RRAs.

iv. **Matter regarding inclusion of Tramadol in the list of Controlled Drugs is referred to Division of Controlled Drug, DRAP.**

Import & Vet-I Section

Case No. 01: Registration of Drugs under the Drugs Act, 1976.

It is submitted that Registration Board in its 331st meeting considered and approved the following imported veterinary products of M/s. Brand Station, 69 Wocland Villas Lahore, Near Raiwind Road, Lahore per following details:

S. No.	Name of Importer/ Manufacturer	Name of Drug(s) & Composition
1.	M/s. Brand Station, 69 Wocland Villas Lahore, Near Raiwind Road, Lahore./ Manufacturer & Marketing Authoization Holder:- M/s. Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam.	Doxycyline 50% Oral Soluble Powder Each gram contains:- Doxycycline Hyclate…….500mg
2.		Linco 4.4% Feed Premix Each gram contains:- Lincomycin HCl……44mg
3.		Tilco 250 Oral Solution Each ml contains:- Tilmicosin as Tilmicosin Phosphate……250mg
4.		Neotesol Water Soluble Powder Each gram contains:- Neomycin Sulphate……..720mg

The address of manufacturer was different in minutes and free sale certificate. The details are as under:-

Address mentioned in Minutes	Address mentioned in Free Sale Certificate/Inspection report/GMP.
M/s. Thien Quan Joint Stock Company, 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam.	M/s. Thien Quan Joint Stock Company, 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam. Factory Address: M/s. Thien Quan Joint Stock Company, Lot 17F2-17F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy diostrict, Can Tho City, Vietnam.

Registration letters issued as per address mentioned in FSC/GMP and case is submitted for information of Registration Board.

Decision: Registration Board noted the information.

Case No. 02: Registration of Drugs under the Drugs Act, 1976/DRAP Act 2012

Registration Board in its 330th meeting considered and approved below mentioned products in the name of M/s. Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan. During process for issuance of registration letters the firm has informed that approved compositions are not correct as per applied drugs. The firm has informed that composition mentioned in minutes is typing error in DRAP Minutes. The firm has provided copy of R&I receiving as evidence.

S. No.	Name of Drug(s) & Composition approved in 330th meeting	Demand Composition/Applied by the firm	Approved Pack Size(s)
1.	Floristin-10 Oral Solution Each ml contains:- Florfenicol……..….1mg Colistin Sulphate……...25mg	Floristin-10 Oral Solution Each 100ml contains:- Florfenicol……..…10gm Colistin Sulphate……..2.5gm	100ml 250ml 450ml 500ml 1000ml

2.	Floristin-25 Oral Solution Each ml contains:- Florfenicol…….250mg Colistin Sulphate….500,000IU	Floristin-25 Oral Solution Each 100ml contains:- Florfenicol…….25gm Colistin Sulphate…….50MIU	100ml 250ml 450ml 500ml 1000ml
3.	Floristin-23 Oral Solution Each ml contains:- Florfenicol……...…230gm Colistin Sulphate…500,000IU	Floristin-23 Oral Solution Each 100ml contains:- Florfenicol……..…23gm Colistin Sulphate…….50MIU	100ml 250ml 450ml 500ml 1000ml

The firm has requested for issuance of registration letters as per applied composition. Firm has submitted R&I receiving and generic status of demanded composition.

Decision: Registration Board acceded to the request of the firm with correction of minutes as per the applied formulations.

Case No.03. <u>REQUEST OF M/S. CHAKWAL PHARMA INTERNATIONAL, LAHORE CANTT FOR REGISTRATION OF VALCYTE 450MG TABLETS TO THEIR NAME FROM M/S BIO VISION CORPORATION, LAHORE.</u>

M/s.Chakwal Pharma International, O.T.I Plaza Basement Ground, 1st, 2nd & 3rd Floor, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, District Lahore has submitted an application for Registration of following already registered products from M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore) to their name. Detail of each proposed product is as under: -

Product:		**Doxipan 20 Water Soluble Powder (Reg.No. 093609)**	
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. Letter** Doxipan 20 Water Soluble Powder Each gram contains:- Doxycycline Hydrochloride….200mg (USP Specifications)	**As per CoPP:** Doxipan 200 mg/g Oral Soluble Powder (named Doxipan 20 in the importing country), Doxycycline hydrochloride (as Hyclate), 800mg/g
	Reg. date / renewal status	Reg. Letter issued on 08-11-2018 Renewal due date 07-11-2023	
	Name and address of Applicant(Transferee)	M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt	
	Name of Transferor	M/s Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)	
	Detail of Drug Sale License	**DSL No. 05-352-0066-023933D (valid upto 13-11-2023)** **Address:** M/s Chakwal Pharma International, O.T.I Plaza Basement Ground, 1st, 2nd & 3rd Floor, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, District Lahore.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy.	**As per CoPP (157/2023/C):** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer:**

		Manufacturer: M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.	M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).
	Name of exporting Country	Italy	
	Diary No. & Date of R& I	Dy. No. 25178 Dated 16/10/2023.	
	Finished Product Specification	USP Specifications approved on 08-11-2018.	
	Shelf life	02 Years	
	MRP/Pack Size	De-controlled (as per Reg. Letter)	
Product:		**Trimethosulfa Orale Oral Solution (Reg.No. 093228)**	
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
2.	Product Name/ Composition	**As per Reg. Letter** Trimethosulfa Orale Oral Solution Each ml Oral Solution contains:- Sulphadiazine……..200mg Trimethoprim……..40mg	**As per CoPP:** Trimethosulfa Orale Oral Solution Each ml Oral Solution contains:- Sulphadiazine……..200mg Trimethoprim……..40mg
	Reg. date / renewal status	Reg. Letter issued on 24-10-2018 Renewal due date 23-10-2023	
	Name and address of Applicant(Transferee)	M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt	
	Name of Transferor	M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)	
	Detail of Drug Sale License	**DSL No. 05-352-0066-023933D (valid upto 13-11-2023)** **Address:** M/s. Chakwal Pharma International, O.T.I Plaza Basement Ground, 1st, 2nd & 3rd Floor, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, District Lahore.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer**: M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.	**As per CoPP (157/2023/C):** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer:** M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).
	Name of exporting Country	Italy	
	Diary No. & Date of R& I	Dy. No. 25180 Dated 16/10/2023.	
	Finished Product Specification	As per Innovator's Specifications approved on 24-10-2018.	
	Shelf life	03 Years	
	MRP/Pack Size	De-controlled (as per Reg. Letter)	
Product:		**AMOXID Water Soluble Powder (Oral Water Soluble Powder) (Reg.No. 093229)**	
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	

<table>
<tr><td rowspan="9">3.</td><td>Product Name/ Composition</td><td>As per Reg. Letter
AMOXID Water Soluble Powder
Oral Water Soluble Powder
Each gram contains:-
Amoxicillin Trihydrate….800mg
(eq. to Amoxicillin base 696.8mg)
(USP Specifications)</td><td>As per CoPP:
AMOXID Water Soluble Powder, Amoxicillin trihydrate, 800 mg/g, equal to Amoxicillin base 696.8 mg/g</td></tr>
<tr><td>Reg. date / renewal status</td><td colspan="2">Reg. Letter issued on 24-10-2018
Renewal due date 23-10-2023</td></tr>
<tr><td>Name and address of Applicant(Transferee)</td><td colspan="2">M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt</td></tr>
<tr><td>Name of Transferor</td><td colspan="2">M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)</td></tr>
<tr><td>Detail of Drug Sale License</td><td colspan="2">DSL No. 05-352-0066-023933D (valid upto 13-11-2023)
Address:
M/s Chakwal Pharma International, O.T.I Plaza Basement Ground, 1st, 2nd & 3rd Floor, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, District Lahore.</td></tr>
<tr><td>Name and address of Manufacturer / Product License Holder</td><td>As per Reg. Letter.
Product License Holder.
M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy.

Manufacturer:
M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.</td><td>As per CoPP (157/2023/C):
Product License Holder.
M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy.
Manufacturer:
M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).</td></tr>
<tr><td>Name of exporting Country</td><td colspan="2">Italy</td></tr>
<tr><td>Diary No. & Date of R& I</td><td colspan="2">Dy. No. 25179 Dated 16/10/2023.</td></tr>
<tr><td>Finished Product Specification</td><td colspan="2">As per Innovator’s Specifications approved on 24-10-2018.</td></tr>
<tr><td>Shelf life</td><td colspan="2">02 Years</td></tr>
<tr><td>MRP/Pack Size</td><td colspan="2">De-controlled (as per Reg. Letter)</td></tr>
</table>

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.150,000/-per product.
b) Copy of Registration letter as mentioned above table.
c) Original & Legalized CoPP issued by Italy.
d) Original Legalized of Letter of authorization in the name of M/s. Chakwal Pharma International, O.T.I Plaza Basement Ground, 1st, 2nd & 3rd Floor, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, District Lahore from Product License Holder.
e) Original Legalized Termination letter from Product License Holder in the name of M/s Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore).
f) Undertaking.

Remarks of Evaluation:

Copy of Last renewal.

Composition of Doxipan as per initial registration letter and CoPP is not same, clarify.

Decision: Registration Board considered the case and decided to issue show cause notice to the M/s Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore that why not the registrations in your name be cancelled as MAH aborad has terminated the sole agency afreement with your firm.

Import & Vet-II Section

Case No.01: **CANCELLATION OF REGISTRATIONS AS DRUGS OF M/S ALI GOHAR & COMPANY (PVT) LIMITED, KARACHI.**

M/s Ali Gohar & Company (Pvt) Limited, Plot No.B-23, SITE Area, Karachi has stated that their following product registered as drugs as per following details: -

S. No.	Reg. No.	Name of product	Pack Size	Initial date of Registration	Last renewal
1.	044834	Systane Lubricant Eye Drops. Contains:- Polyethylene Glycol 400……0.4% w/v. Propylene Glycol …0.3% w/v.	15ml. 30ml	01-02-2007 24-09-2007 (Additional Pack)	27-12-2021
2.	023129	Tears Naturale Eye Drops Each ml contains dextran 70----1.0mg, sodium cholride 6.0mg, borax 3.5MG, potassium chloride 1.2mg, concentrated Hcl acid pohyquaterniom -1 0.01mg	15ml droptainer	27-02-1999	06-11-2023

Now the firm has requested to cancel / de-registered above products as from Drug Registration status.

Firm has provided following supporting documents: -

a) Application with fee of Rs.7,500/- for each pack size.
b) Copies of initial registration letter and renewal trail.
c) Valid copy of DSL (10-04-2028).

Firm has informed that products are no longer classified as pharmaceutical products and have been re-classified as Medical Devices in the country of Origin.

Firm has provided copies of Letter of Authorization in the name of M/s Medzntech (Pvt) Ltd, D-21, Sector 16-A, Govt. Teachers Co-Operative Housing Society, K.D.A., Scheme-33, Karachi and copy of termination of distribution agreement between Alcon Pharmaceuticals Ltd & M/s Ali Gohar & Company (Pvt) Limited.

M/s Ali Gohar & Company (Pvt) Limited, Karachi has requested for approval of de-registration of products which is a requirement for processing the case for enlistment / new registration of the same products as imported medical devices by M/s Medzntech (Pvt) Ltd, Karachi.

Decision:
The Registration Board considered & approved the request of M/s Ali Gohar & Company (Pvt) Limited, Plot No.B-23, SITE Area, Karachi for de-registration of following products:-

S. No.	Reg. No.	Name of product	Pack Size	Initial date of Registration
1.	044834	Systane Lubricant Eye Drops. Contains:- Polyethylene Glycol 400……0.4% w/v. Propylene Glycol …0.3% w/v.	15ml. 30ml	01-02-2007 24-09-2007 (Additional Pack)
2.	023129	Tears Naturale Eye Drops Each ml contains dextran 70----1.0mg, sodium cholride 6.0mg, borax 3.5MG,	15ml droptainer	27-02-1999

		potassium chloride 1.2mg, concentrated Hcl acid pohyquaterniom -1 0.01mg		

Case No.02. <u>REQUEST OF M/S ALI GOHAR & COMPANY (PVT) LTD, KARACHI FOR REGISTRATION OF VALCYTE 450MG TABLETS TO THEIR NAME FROM M/S ROCHE PAKISTAN LIMITED, KARACHI.</u>

M/s Ali Gohar & Company Private Limited, Plot No. B-23, SITE, Karachi has submitted an application for Registration of following already registered product from M/s Roche Pakistan Limited, 37-C, Block 6, P.E.C.H.S., Karachi to their name. Detail of each proposed product is as under: -

Product: Valcyte Tablet 450mg (Reg.No. 052253)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. Letter** Valcyte Tablet 450mg. Each film coated tablet contains:- Valganciclovir HCL…..450mg	**As per CoPP:** Valcyte, Film Coated Tablet Valganciclovir, 450mg
	Reg. date / renewal status	Reg. Letter issued on 11-11-2008 Renewal granted w.e.f.11-11-2018 to 10-11-2023. Approval for change of Specification to Manufacturer Specifications on 19-04-2020. Renewal due date 10-11-2023 Renewal submit on 27-10-2023.	
	Name and address of Applicant(Transferee)	M/s Ali Gohar & Company Private Limited, Plot No. B-23, SITE, Karachi.	
	Name of Transferor	M/s Roche Pakistan Limited, 37-C, Block 6, P.E.C.H.S., Karachi.	
	Detail of Drug Sale License	**DSL No.DHO Keamari/(drugs)-85 (valid upto 10-04-2028)** **Address:** M/s Ali Gohar & Company Private Limited, Plot No. B-23, SITE Area, Karachi.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Manufacturer**: M/s Patheon Inc., Canada	**As per CoPP (310.130.01.12-125/2022):** **Product License Holder.** M/s Cheplapharm Arzneimittel GmbH Ziegelhof 24 17489 Greifswald, Germany. **Manufacturer:** M/s Patheon Inc. 2100 Syntex Court Mississauga, Ontario L5N 7K9, Canada.
	Name of exporting Country	Germany	
	Diary No. & Date of R& I	Dy. No. 29173 Dated 18/12/2023.	
	Finished Product Specification	Manufacturer Specifications approved on 19-04-2020.	
	Shelf life	03 Years	
	MRP/Pack Size	Rs.106,080/60's (as per Reg. Letter)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

g) Application with a fee of Rs.150,000/-.
h) Copy of Registration letter, variation and renewal trail, detail as mentioned above table.
i) Original & Legalized CoPP issued by Germany.
j) Original Legalized of Letter of authorization in the name of M/s Ali Gohar & Company (Private) Limited, State Life Building 1-B, I.I., Chundrigar Road, Karachi from Product License Holder.
k) Original Legalized Termination letter from Product License Holder in the name of M/s Roche Pakistan Limited, 1st Floor, 37-B, Block 6, P.E.C.H.S., Main Shahrah-e-Faisal, Karachi.
l) Original NOC (Ref.No.070/2023/SS-DRAP) for transfer of registrations from M/s Roche Pakistan Limited, Karachi **(issued on 29-11-2023).**

m) Undertaking.

Decision: -

Keeping in view the above position, Registration Board decided to approved the change of importer/ MA holder in Pakistan for Valcyte Tablet 450mg (Reg.No. 052253) from the name of M/s Roche Pakistan Limited, 37-C, Block 6, P.E.C.H.S., Karachi to the name of M/s Ali Gohar & Company Private Limited, Plot No. B-23, SITE, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).

Case No.03. REGISTRATION OF CELONIB 100 CPSULES.

Registration Board in its 226th meeting considered and approved the following product of M/s Hakimsons (Impex) (Pvt) Ltd. Karachi as per following details: -

M/s. Hakimsons (Impex) (Pvt) Ltd. Karachi / M/s. Celon Laboratories Limited, India.	Celonib 100 Capsule Each capsule contains : - Imatinib Mesylate ....120 mg Lactose Anhydrous USNF.....30mg Avicel pH 101/102 .49.7 mg Crospovidone USNF...20 mg Colloidal Silicon Dioxide...5mg Talc BP ..... 2 mg Magnesium Stearate USNF…3mg EHG Capsules Size 1 .. One (Antineoplastic)	Rs. 136000/- per pack of 12x10s	2 years	Approved

Inspection of the manufacturer abroad M/s Celon Laboratories Limited, India was carried out by the nominated panel comprising of Mr. Muhammad Akhtar Abbas Khan, Deputy Director General, DRAP, Islamabad &Dr. Najam-us-Saqib Mughal,, Deputy Director General, DRAP, Karachi on 3rd& 4th May, 2013 and the panel rated the manufacturing facility as **"Good"** (recommended).

A clarification letter to the firm is issued (18-09-2020) as under:

"With reference to your applications on the subject cited above. It is to inform you that during processing the case, it is noted that Celonib 100 capsule discussed in 226th meeting of Registration Board as per minutes Product is Imatinib mesylate 120mg while as per CoPP it is Imatinib mesylate eq. Imatinib 100mg. You are hereby advised to clarify above mentioned position with supporting documents for further processing the matter".

Decision: -

Keeping in view the above position, Registration Board acceded the firm request and decided to approve the product Celonib 100 capsule in accordance with details of composition and manufacturer as per CoPP.

Case No.04 REQUEST OF M/S FRESENIUS MEDICAL CARE PAKISTAN (PVT) LTD, LAHORE FOR EXEMPTION FROM LABELLING REQUIREMENTS ON IMPORTD PRODUCTS.

M/s Fresenius Medical Care Pakistan (Pvt) Ltd, 27-C, 1st Floor, TAMC Building, MM Alam, Gulberg-III, Lahore has requested for exemption from printing of Urdu version label and allow us to print below mentioned information locally for one year. details are as under: -

Details of Products:

Reg. No.	Name of Product	Remarks
114282	Multibic potassium free Solution for Haemodialysis/Haemofiltration	D.No.711-R&I dated 11-01-2024 & D.No.3181-R&I dated 20-02-2024
114279	Multibic 2 mmol/l potassium Solution for Haemodialysis / Haemofiltration.	Reg. Letter date 17-08-2023

114281	Multibic 3 mmol/l potassium Solution for Haemodialysis / Haemofiltration.	
114280	Multibic 4 mmol/l potassium Solution for Haemodialysis / Haemofiltration	

The firm has requested to allow them to print the following components on outer box of product locally for a period of One Year at licensed premises i.e. M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Raiwind Road, Lahore DML No. 000840 as per labeling and packaging Rules 1986.

- Name and complete address of importer.
- Registration number.
- Maximum retail price.

The firm has provided the following supporting documents along with the application: -

a. Fee challan of Rs.10,000/- for each product.
b. Copy of registration letter.
c. Copy of Drug Manufacturing License (No.000840) (M/s Cunningham) valid 01-06-2021 (acknowledgment for renewal of the same provided).
d. Copy of valid DSL (M/s Fresenius) No.05-352-0065-103893D (valid upto 10-04-2028).
e. Agreement between M/s Fresenius Medical Care Pakistan (Pvt) Ltd, 27-C, 1st Floor, TAMC Building, MM Alam, Gulberg-III, Lahore AND M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000840).

Decision:

Registration Board acceded to the request for import of following already registered products in Standard Int. Packs of M/s Fresenius Medical Care Pakistan (Pvt) Ltd, 27-C, 1st Floor, TAMC Building, MM Alam, Gulberg-III, Lahore. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at Licensed Premises (DML No.000840-M/s Cunningham Pharmaceuticals Private Limited, Plot No.81, Sunder Industrial Estate, Lahore) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one (01) year only. The firm shall submit the plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

S. No.	Reg. No.	Name of Product
1.	114282	Multibic potassium free Solution for Haemodialysis/Haemofiltration
2.	114279	Multibic 2 mmol/l potassium Solution for Haemodialysis / Haemofiltration.
3.	114281	Multibic 3 mmol/l potassium Solution for Haemodialysis / Haemofiltration.
4.	114280	Multibic 4 mmol/l potassium Solution for Haemodialysis / Haemofiltration

Case No.05 REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LTD, KARACHI FOR IMPORT REGISTERED PRODUCTS IN GENERAL EXPORT PACK/ OVERPRINTING OF LABELLING TEXT LOCALLY.

M/s Glaxosmithkline Pakistan Ltd, F-268, SITE, Karachi has requested for import of registered products in general export pack / overprinting of labelling text locally. Details are as under: -

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
1.	043090	Duac Once Daily Gel Contains:-	D.No.2812-R&I dated 14-02-2024 Dy.No.3452-R&I dated 23-02-2024

		Clindamycin Phosphate 1.28%w/w. Hydrous Benzoyl Peroxide 6.67%w/w	Duac Once Daily Gel Reg. Letter issued on 04-11-2006. Approval for transfer of registration to GSK Pakistan Limited on 23-08-2011. Approval for change in importer address to F-268, SITE, Karachi on 12-10-2021.
2.	014918	Lamictal tablets 25mg Each tablet contains: - Lamotrigine……..25mg=	Lamictal Tablet 25, 50mg & 100mg • Reg. Letter (Beecham Pak Ltd) 24-02-1994 • Change of firm name (GSK Pak Ltd,35-Dockyard) 08-09-2003. • Approval for change in importer address to F-268, SITE, Karachi on 12-10-2021. • Approval for change of Manf. Site on 06-12-2023. • Renewal due date 07.09.2023 • Last Renewal on 04.09.2023
3.	014919	Lamictal tablets 50mg Each tablet contains: - Lamotrigine…… 50mg	
4.	014921	Lamictal tablets 100mg Each tablet contains:- Lamotrigine…….100mg	
5.	019532	Lamictal tablets (Dispersible/chewable) 5mg Each tablet contains: - Lamotrigine…… 5m	Lamictal Tablet 5mg • Reg. Letter (Wellcome Pak Ltd) 15-01-1999. • Change of firm name (GSK Pak Ltd,35-Dockyard) 08.09.2003. • Approval for change of Manf. Site on 06-12-2023. • Approval for change in importer address to F-268, SITE, Karachi on 12-10-2021. • Renewal due date 07.09.2023 • Last Renewal on 04.09.2023

The firm has requested to grant us exemption from printing of Urdu version label and allow us to print below mentioned information locally for three years at Licensed warehouse of M/s GSK Pkistan, F-268 (DML No.000233).

- Local text.
- Registration number.
- Maximum retail price.

The firm has provided the following supporting documents along with the application: -

a. Fee challan of Rs.10,000/- for each product.
b. Copy of registration letter.
c. Copy of valid DSL No.008 (valid upto 04-10-2024)
d. Copy of valid Drug Manufacturing License of M/s GSK Pakistan, F-268 (DML No.000233).

Decision:

Registration Board acceded to the request for import of following already registered products in Standard Export Packs of M/s Glaxosmithkline Pakistan Ltd, F-268, SITE, Karachi. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000233- M/s Glaxosmithkline Pakistan Ltd, F-268, SITE, Karachi) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one year only. The firm shall submit the plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

S. No.	Reg. No.	Name of Product
1.	**043090**	**Duac Once Daily Gel Contains:- Clindamycin Phosphate 1.28%w/w. Hydrous Benzoyl Peroxide 6.67%w/w**
2.	**014918**	**Lamictal tablets 25mg Each tablet contains: -**

		Lamotrigine……..25mg
3.	**014919**	**Lamictal tablets 50mg** **Each tablet contains: -** **Lamotrigine…… 50mg**
4.	**014921**	**Lamictal tablets 100mg** **Each tablet contains:-** **Lamotrigine…….100mg**
5.	**019532**	**Lamictal tablets** **(Dispersible/chewable) 5mg** **Each tablet contains: -** **Lamotrigine…… 5mg**

Case No.06 **REQUEST OF M/S BAYER PAKISTAN (PVT) LTD, KARACHI FOR CONVERSION OF COMMERCIAL PACKS (IMPORTED PRODUCT) PRIMOVIST PFS (1'S X 10ML) INTO PHYSICIAN SAMPLES-NOT FOR SALE.**

M/s Bayer Pakistan (Pvt) Ltd, Korangi Industrial Area, Plot No.23, Sector No.22, Karachi requested that they will convert commercial packs of their imported product "Primovist Injection (Reg. No.) into physician samples by doing following activities at their registered facility (warehouse).

a) Printing of text i.e. "Physicians Sample not for sale"
b) Masking of MRP as samples are not intended for sale.

This activity does not adversely impact the quality, efficacy, or safety of the product. Further, to note that considering the nature of the product, packing cannot be reduced.

Decision: Registration Board did not accede the information.

Case No.07 **REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR PERMISSION TO IMPORT INTERNATIONAL PACKS OF REGISTERED PRODUCTS.**

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has stated that manufacturer of their registered products has informed that due to very specific and limited quantity of products they are unable to provide this medicine in country specific packs. Detail of products is as under

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
1.	115716	Sandostatin 0.1mg Solution for Injection or Infusion Each ml contains: Octreotide….0.1mg As per Innovators Specifications*	Dy.No.2546-R&I dated 07-02-2023 Reg. Letter date 20-10-2023.
2.	115717	Sandostatin 0.05mg Solution for Injection or Infusion Each ml contains: Octreotide….0.05mg As per Innovators Specifications*	
3.	084161	Votrient Tablets 200mg Each film coated tablet contains:- Pazopanib (as hydrochloride)…….200mg	Copy of registration letter issued on 07-04-2017. Approval for change in manufacturer on 30-04-2022. Renewal due date 06-04-2022 Renewal submit on 18-03-2022
4.	084162	Votrient Tablets 400mg Each film coated tablet contains:- Pazopanib (as hydrochloride)…….400mg	

5.	001958	Desferal Injection 500mg Each freeze-dried vial contains: Deferoxamine mesylate…500mg	Reg. letter on 11-06-1977 Renewal due date 10-06-2022 Renewal submit on 18-05-2022

The firm has requested to allow them to print the following components on outer box of product locally at licensed premises i.e. C-21, SITE, Karachi DML No. 000003 as per labeling and packaging rules 1986.

- Urdu text.
- Registration number.
- Maximum retail price.
- Name and address of sole agent.
- 2D Matrix Barcode
- Other information (as per labeling requirements)

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.10,000/- for each product.
b. Copy of registration letter, PRVC approvals & renewal trail.
c. Copy of valid DML.

Decision:

Registration Board acceded to the request for import of following already registered products in Standard Export Packs of M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000003- M/s Novartis Pharma Pakistan Ltd, C-21, SITE, Karachi) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one year only. The firm shall submit the plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

S. No.	Reg. No.	Name of Product
1.	**115716**	**Sandostatin 0.1mg Solution for Injection or Infusion Each ml contains: Octreotide….0.1mg As per Innovators Specifications***
2.	**115717**	**Sandostatin 0.05mg Solution for Injection or Infusion Each ml contains: Octreotide….0.05mg As per Innovators Specifications***
3.	**084161**	**Votrient Tablets 200mg Each film coated tablet contains:- Pazopanib (as hydrochloride)…….200mg**
4.	**084162**	**Votrient Tablets 400mg Each film coated tablet contains:- Pazopanib (as hydrochloride)…….400mg**
5.	**001958**	**Desferal Injection 500mg Each freeze-dried vial contains: Deferoxamine mesylate…500mg**

Case No.08 REQUEST OF M/S ROCHE PAKISTAN LIMITED, KARACHI FOR WITHDRAWAL OF GAVRETO 100MG CPSULE.

The subject product considered & approved in 317th meeting of Registration Board held on 16th & 17th May, 2022 as per following: -

Name of Importer / Manufacturer	Name Drug(s)	Remarks

<table>
<tr>
<td>M/s Roche Pakistan Limited,
1st floor, 37-B, Block 6, PECHS, Karachi.
Address of Godown:
R-PI, plot no. 116, sector 15, K.I.A, Karach
Marketing Authorization Holder
M/s Genentech, Inc. (A member of the Roche group), 1 DNA Way, PDRO building 35, MS 355J, South San Francisco, CA 94080 United States of America.
Name, address of finished drug product manufacturer(s):
<table>
<tr><th>Name and Address of Site</th><th>Activities Occurring at Site</th></tr>
<tr><td>Catalent CTS, LLC
10245 Hickman Mills Drive
Kansas City, Missouri (MO) 64137, United States (USA)</td><td>Pralsetinib Capsules (bulk) Manufacturing
Release Testing
Stability Testing
Bulk Capsules Packaging</td></tr>
<tr><td>Anderson Brecon Inc. (PCI Pharma Services) 4545 Assembly Drive, Rockford, Illinois (IL) 61109, United States (USA)</td><td>Primary and Secondary Packaging and Labeling
Batch Release</td></tr>
<tr><td>F. Hoffmann-La Roche AG, Contract Organizations, Viaduktstrasse 33, CH-4051 Basel Switzerland</td><td>Batch Release</td></tr>
</table>
</td>
<td>Gavreto 100mg capsule
Each capsule contains:
Pralsetinib…….100mg

Kinase inhibitor
Innovator’s specifications</td>
<td>As per SRO

60 capsules
90 capsules
120 capsules

Referred to C&P Division for fixation of MRP</td>
</tr>
<tr><td colspan="3">Decision M-317: Approved with Innovator’s specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.</td></tr>
</table>

Now, firm has submitted request for withdrawal of the same and stated that Their Principal, F.Hoffmann-La Roche Ltd, Basel Switzerland, has formally requested the withdrawal of the registration application for Gavreto in all countries where this product was intended to be marketed. This request follows the termination of the global collaboration between Roche and Blueprint Medicines for the commercialization of Gavreto worldwide. Therefore, in light of these recent strategic decisions and the divestment of global rights to the product license, we find it necessary to proceed with the withdrawal of the registration.

Decision: -
Keeping in view the above position, Registration Board acceded the firm request withdrawal of product “Gavreto 100mg capsule (approved in 317th meeting of Registration Board)

Case No: 09 <u>REQUEST OF M/S AMTUL PHARMACEUTICALS, LAHORE REGISTRATION OF DRUGS (OMULCER 40MG INJECTION) UNDER THE DRUGS ACT, 1976.</u>

The subject case was discussed in 320th meeting of Registration Board as under: -

Registration Board in its 261st meeting approved the following product of M/s. Amtul Pharmaceuticals, Lahore as per decision mentioned alongside each;

Importer M/s. Amtul Pharmaceuticals, 251-Sikandar Block Allama Iqbal Town, Lahore Manufacturer: M/s Reyoung Pharmaceutical Co.No.6, Erlangshan Road,Yiyuan County,Shandong Province, P.R. China. Priority # 85	Omulcer 40mg Injection Each vial of lyophilized powder contains:- Omeprazole Sodium 40mg Proton Pump Inhibitior Specifications:- Manufacturer	Pack size one vial Rs. 750/-	Approved as per Import Policy for Finished Drugs.

Now, M/s AMB HK Enterprises (Pvt) Ltd, Lahore has submitted request for registration of above product on their name and submitted following documents: -

- Original cancellation letter from REYOUNGE to M/s Amtul Pharmaceuticals, Lahore.
- Original agreement of REYOUNGE with M/s AMB HK Enterprises (Pvt) Ltd, Lahore.
- Original CoPP for Omeprazole 40mg Injection.

In view of above, a letter vide No.F.1-8/2020-I&V-II/Human Import dated 31st May, 2022 & reminder for the same dated 24th August, 2022 was conveyed to the firm and advised to submit fresh sole agency agreement letter in your name form product license holder and no reply from the M/s Amtul Pharmaceuticals, Lahore received.

Decision M-320: Registration Board considered the case and decided to issue a reminder to M/s. Amtul Pharmaceuticals, Lahore for submission of fresh sole agency agreement letter in their name form product license holder.

Proceedings of 327th meeting: The Board was apprised that M/s Amtul Pharmaceuticals had not submitted requisite documents as per decision of 261st meeting of Registration Board wherein the application was decided as "Approved as per Import Policy for Finished Drugs". The Board was further apprised that a reminder was issued to M/s Amtul Pharmaceuticals for submission of fresh sole agency agreement letter in their name from product license holder as per decision of 320th meeting of Board but till date the firm has failed to submit required documents.

Decision M-327: Registration Board while considering the above cited facts decided to withdraw the approval of 261st meeting in name of M/s. Amtul Pharmaceuticals, 251-Sikandar Block Allama Iqbal Town, Lahore for the "Omulcer 40mg Injection" and directed the I&V-II section for evaluation of M/s AMB HK Enterprises (Pvt) Ltd, Lahore application.

M/s AMB HK Enterprises (Pvt) Ltd, Lahore application on form -5F (26-11-2021) with fee Rs. 150,000/- is complete for registration of above product on their name along with following documents: -

Name, address of Applicant / Importer	M/s AMB HK Enterprises (Pvt) Ltd, 2nd floor Plaza 60, commercial block K, Phase-1 DHA, Lahore
Details of Drug Sale License of importer	License No: 05-352-0058-104514D Status: Drug License by way of wholesale
Name and address of marketing authorization holder (abroad)	Reyoung Pharmaceutical Co., Ltd. Workshop 206, No 1, Ruiyang Road, Yiyuan County, Shandong Province, P.R. China
Name, address of manufacturer(s)	
Name of exporting country	China.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Application Form, Dy. No / Tracking ID & date of submission	Form 5F:
Details of fee submitted	PKR 150,000/-
The proposed proprietary name / brand name	Omulcer 40mg Injection

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of lyophilized powder contains:- Omeprazole Sodium 40mg Sterilised Water for Injection 10ml
Pharmacotherapeutic Group of (API)	Proton Pump Inhibitior
Reference to Finished product specifications	USP
The status in reference regulatory authorities	(MHRA Approved)
For generic drugs (me-too status)	Risek-Getz
Proposed Pack size	As per SRO/ 1 vial + 1ampoule
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP (No. 2021120002) from NMPA china dated 06-12-2023
Details of letter of authorization / sole agency agreement	Firm has submitted Contract of Agency between Reyoung Pharmaceutical Co., Ltd and M/s AMB HK Enterprises (Pvt) Ltd dated 27-08-2019

Decision: -
Keeping in view the above position, Registration Board acceded the firm request for registration of "Omulcer 40mg Injection" in accordance with details of composition and manufacturer as per CoPP.

Case No.10. <u>REQUEST OF M/S BAYER PAKISTAN (PRIVATE) LIMITED, LAHORE FOR CHANGE IN IMPORTER ADDRESS AND CHANGE OF MANUFACTUIRNG SITE (TO FINISH IMPORT).</u>

M/s Bayer Pakistan (Pvt) Ltd, Lahore has submitted request for change in importer address and change in manufacturing site of product "Nimotop tablet" as per following details:-

Details of change in importer address:

S. No.	Name of Document	Details as per Reg. Letter	Details as per New DSL (NO. DHOKK/101/23) valid upto 04-05-2028
1.	**Current Name & address Importer**	M/s Bayer Pakistan (Pvt) Ltd, Plot No. 108, Quaid-e-Azam Industrial Estate, Lahore.	M/s Bayer Pakistan (Pvt) Ltd, Plot No.23 Sector 22, Korangi Industrial Area, Karachi. **Godown:** Plot No.32-12, Sector 19, Korangi Industrial Area, Karachi.
Dy. No.26204-R&I dated 30-10-2023. Dy. No.4850-R&I dated 06-05-2024.			

Details of change in manufacturing:

Reg. No.	Name & Composition	Existing approved Site as per Reg. Letter (31-03-2023)	Proposed Sites
107223	Nimotop 30mg Tablet Each film coated tablet contains: - Nimodipine….30mg (Manufacturer's Specifications)	**Contract manufacturing basis:-** M/s Novartis Pharma, C-21, SITE, Karachi	**Bulk Manufacturing, Quality Control Testing and Release by:-** M/s Bayer AG, Kaiser-Willhelm-Allee, 51368, Leverkusen, Germany **Primary and Secondary Packaging by:** M/s Haupt Pharma Munster Gmbh, Schleebruggenkamp 15 48159 Muenster, Germany.

Firm has submitted following supporting documents: -

a) A fee of Rs.150,000/- dated 30-10-2023.
b) Copy of registration letter.
c) Original & Legalized CoPP issued by Germany.
d) Original Sole Agency Declaration.
e) Copy of New Drug Sale License valid upto 04-05-2028
f) An undertaking.

Decision:
Registration Board deliberated the matter and decided to approve the change in registration status from bulk import to finish import along with change in manufacturing site with change in importer address for following product:-

Detail of change in Importer

Details as per Reg. Letter	Details as per New DSL (NO. DHOKK/101/23) valid upto 04-05-2028
M/s Bayer Pakistan (Pvt) Ltd, Plot No. 108, Quaid-e-Azam Industrial Estate, Lahore.	M/s Bayer Pakistan (Pvt) Ltd, Plot No.23 Sector 22, Korangi Industrial Area, Karachi. **Godown:** Plot No.32-12, Sector 19, Korangi Industrial Area, Karachi.

Details of change in manufacturing with bulk to finish import:

Reg. No.	Name & Composition	Existing approved Site as per Reg. Letter (31-03-2023)	Proposed Sites
107223	Nimotop 30mg Tablet Each film coated tablet contains: - Nimodipine….30mg (Manufacturer's Specifications)	**Contract manufacturing basis:-** M/s Novartis Pharma, C-21, SITE, Karachi	**Bulk Manufacturing, Quality Control Testing and Release by:-** M/s Bayer AG, Kaiser-Willhelm-Allee, 51368, Leverkusen, Germany **Primary and Secondary Packaging by:** M/s Haupt Pharma Munster Gmbh, Schleebruggenkamp 15 48159 Muenster, Germany.

Case No.11: <u>REGISTRATION OF PRODUCT OF M/S IQBAL & COMPANY, ISLAMABAD.</u>

Subject case was discussed in 320th meeting of Registration Board as under: -

Registration Board in its 291st meeting approved the following product of M/s Iqbal & Company, 1st floor, Al-Falah Manzil, Opp. National Police Foundation, St. No. 26, Sector E-11/4, Islamabad as per decision mentioned alongside.

Name of Importer/Manufacturer	Product Name & Composition	Demanded Pack size & MRP
M/s Iqbal & Company,1st floor, Al-Falah Manzil, Opp. National Police Foundation, St.No. 26, Sector E-11/4, Islamabad **Marketing Authorization Holder:** M/s Gambro Lundia AB Box ,Magistratsvagen 16, Lund, SE-22643, Sweden **Manufacturer:**	HEMOSOL B0 Solution for Haemodialysis/ Haemofiltration Each ml of 2 compartment bag contains: Medimar Electrolyte solution (Small Compartment A-250ml) lactic acid ……. 5.4mg Calcium chloride dehydrate …… 5.145mg Magnesium chloride hexahydrate…. 2.033mg Buffer Solution (Large Compartment B-4750 ml) Sodium Chloride……..…6.450mg	(2 x 5000ml) polyolefin bags, in a box Not proposed

M/s Bieffe Medital S.P.A Via Stelvio 94, 230 35 Sondalo (SO), I-23035, Italy	Sodium hydrogen carbonate…. 3.090mg After Reconstitution Calcium (Ca+2)….. 1.75 mmol/L Magnesium (Mg+2)……0.5 mmol/L Sodium (Na+)…… 140 mmol/L Chloride (Cl-)…….. 109.5 mmol/L Lactate……..... 3 mmol/L Hydrogen carbonate (HCO3-)…….. 32mmol Hemofiltrates BP 18 months (Polyolefin bag)	
Decision: Approved as per policy of inspection of manufacturer abroad.		

Registration Board in its M-293rd meeting deliberated in light of Rule 24 (10) of Drugs (L, R & A) Rules, 1976 and authorized Chairman for nomination of inspector for product storage verification of local premises. Accordingly, Chairman RB nominate to Assistant Director (I&V) & Assistant Director (Reg-II) PE&R Division DRAP, Islamabad to inspect the above local storage facility. Inspection of premises M/s Iqbal & Company,1st floor, Al-Falah Manzil, Opp. National Police Foundation, St. No. 26, Sector E-11/4, Islamabad was conducted on 24th September, 2020 with status **Not Recommended** on the following points: -

Sr.No.	Observations / Shortcomings	Remarks
1.	Checklist for personal safety.	No
2.	Is there a cleaning schedule in place	No
3.	Are all the products are properly placed or arrangments are made for systematic storage	No
4.	Are the temperature logs readily available for a minimum of two years	One week record available
5.	Check the alarm system. Is it ok	No.
6.	Is there any routine and emergency maintenance plan	No
7.	Check if there is any maintenance agreement with an ourside agency	No.
8.	Is routine maintenance being perfomed correctly at the internvals stated in theagreeement	No
9.	When emergencies occur, does the maintennacne technician arrive with the maximum stipulated in the agreement	No.
10.	Does the importer have established the Re-Call system of drugs	No

Furthermore, Ten Cotton of drug HEMOSOL B0 Solution for Haemodialysis/ Haemofiltration which is under registration was found in storage premises of M/s Iqbal & Sons Company.
Accordingly, above position was conveyed to Additional Director (QA/LT) Division vide letter No.F.1-11/2020-I&V-II/Human Import dated 23rd December, 2020 for further necessary action at their end.

Decision of 291st meeting: Registration Board advised QA/LT Division to finalize the case and inform PE&R Division for further processing of case.

Updated Status: -
Area FID-IV has submitted vide letter No.F.4-5/2021-FID(IV) dated 29-07-2022 as under: -

I have honor to refer to the letter No. F- 3-312021-l & VII (M312) there dated 25ft Nov. 2021, which is in continuation to the previous letter No.F.l-lll2}20 (I & VII) Human Import dated 23'd December,2020 on the subject cited above. The detail of the matter /case after scrutiny of the documents is as under:
The Registration Board in its 312 meeting refers the case to QA Division. The firm has submitted documents which have been reviewed in light of decision of Registration Board which indicted the following details for consideration;

i. The firm has applied for the registration of Product namely "Hemosol BO solution for Heamodialysis/Flaemofiltration in 2016. the case was first presented before Registration Board in its 279th meeting.

ii. The case has finally decided by the Registration Board in its 291't meeting as under approved as per policy by the manufacture observed " (copy attached)

iii. Accordingly, Chairman Registration Board constituted the panel for verification of local storage facility comprising of
   a) Assistant Director (I&V)
   b) Assistant Director (Reg-II)

The panel conducted inspection on 24-09-2020 and observed series of shortcoming along with the observation that 10 carton of the same product (viz under registration) was present there but didn't refer the same in the shortcoming for clarification.(copy attached/. The case was referred to QA< Division on 23'd December 2020, (copy attached) mentioning that they have forwarded the pictures of the same to the predecessor FID ,which she explain that information was received on 30-09-2020 (after a weak of inspection) & no written complaint provided with detail so action can't initiated (copy attached). The letter was again received on 25th November 2021 (after laps of almost one year).

The undersigned scrutinized the available documents and Board meetings which indicate that product is categorized as medical Devices in Italy (where actually manufacturing takes place) and referred as medicinal product in Sweden (actual maker authorization holder) (copy attached). The documents further indicate that product actually imported in the year of 2018 &2019 for Shaukat Khanum Hospital (institutional supply (copy attached/ and since its fate at that time was not decided/declare whether it is medical devices or otherwise the firm thus avails the opportunity of category of Medical Devices (as in Italy) and Rules 52 of MEDICAL Device Rules 2018 provide exemption to these class of products which is further amended vide SRO526(1) 12021 and exemption is extended S.R.O NOC not proceeded.(copy attached)

In the light of above in is worth mentioning here that no action from QA&LT Division at this point is required and case may please be processed at the end of Registration Division in the light of provided documents.

Decision 320th meeting of RB:

Registration Board decided to seek legal opinion from Legal Affair Division on the matter.

Legal Opinion:

After perusal of the correspondence of the FID and QA& LT Division with PE&R Division, it has been revealed that the product ***HEMOSOL*** (hereinafter referred to as the ***product***)which is under registration before the Registration Board is categorized as medical Devices in Italy (where actually manufacturing takes place) and referred as medicinal product in Sweden (actual maket authorization holder).

Furthermore, product was imported in the year of 2018 &2019 for Shaukat Khanum Hospital (institutional
supply) since its fate at that time was not decided/declare whether it is medical devices or any other therapeutic goods, therefore, the firm thus avails the opportunity of category of Medical Devices (as it is a Medical Device in Italy) and took the advantage of exemption from registration under ***Rule 52*** of Medical
Device Rules 2017. Therefore, details may be obtained from the importer regarding the NOC issued either
by Medical Devices Division or by the I&E Section of the Head Office or regional offices. Thus the situation
shall become clear before the Registration Board whether import of the product was legal or illegal.

Moreover, Registration Board is a competent forum to decide fate of the product either to register it as Drug or to refer it to MD&MC division in case if it is a medical device.

QA & LT Division:

As per record received from Field office Lahore and Islamabad, no NOC was issued for the referred product to Shaukat Khanum Hospital or any other by Division of QA &LT during the period 2018-2019.

Decision M-324:

Keeping in view position narrated above, Registration Board decided to refer the matter to the DRAP's Grey molecule committee to review the status of product and then submit its recommendations to relevant statutory forum.

Decision: -

Keeping in view the above position, Registration Board deliberated the matter and decided to approve the registration of "HEMOSOL B0 Solution for Haemodialysis/ Haemofiltration" in accordance with details of composition and manufacturer as per CoPP.

Cases referred from 117th PRVC (Human Import)

Case No.12: M/S B. BRAUN PAKISTAN LTD. REQUEST FOR MANUFACTURER SPECIFICATION FOR PROPOFOL LIPURO (REG.NO.033126)

Sr.#	Specification	USP Limits	BP Limits	In House Limits
1.	Appearance	not directly stated	not directly stated	Visual (a white, milky oil-in-water emulsion)
2.	Extractable volume	not directly stated	not directly stated	not less than the nominal volume of the container
3.	Odour	not directly stated	not directly stated	weakly phenol-like
4.	ID: Soya bean oil	not directly stated	not directly stated	complies
5.	ID: Medium-chain triglyceride	not directly stated	not directly stated	complies
6.	ID: Egg lecithin	not directly stated	not directly stated	complies
7.	ID: Glycerol	not directly stated	not directly stated	complies
8.	ID: UV Propofol	Meets the requirements	Meets the requirements	maximum absorption: 270 – 275 nm, shoulder near 280 nm
9.	ID: HPLC Propofol	not directly stated	Meets the requirements	not stated
10.	pH	4.5 – 8.5	6.0 – 8.5	6.0 – 8.5
11.	Microscopic assessment	fat droplet distribution ≤ 5 µm=99.95% fat droplet size =<500nm	not directly stated fat droplet size =<2nm	droplets □ 1 µm not less than 99 p.c. not more than 5 droplets > 2 to □ 10 µm per individual field no droplets > 10 µm
12.	Free fatty acid	□ 7 mmol/l	□ 7 mmol/l	□ 6.0 mmol/l
13.	Lysolecithin	not directly stated	≤ 2.0 g/l	Lysolecithin is a component of egg lecithin and is already tested in the raw material specification of egg lecithin. Egg lecithin itself acts as an emulsifier and serves to stabilize the emulsion. The stability is ensured via the check of the parameters of microscopic assessment, pH value and test on FFA over the stated shelf life of the emulsion. These tested parameters are considered to be sufficient to ensure the quality and stability of the emulsion, which is also confirmed by the non-inclusion of the

				parameter Lysolecithin within the USP monograph.
14.	Globule size distribution	0.05 % v/v < 0.5 µm	≤ 5000 globules ≥ 2 µm/ml	not stated
15.	Peroxide value	not directly stated	not directly stated	□ 1.0
16.	Impurity [E] 3,3', 5,5'-tetrakis(1-methylethyl)biphenyl-4,4'- diol	□ 0.5 %	0.25%	□ 25 ppm
17.	Impurity	□ 0.5 %	0.1%	□ 10 ppm
	[J] 2,6-bis(1-methylethyl)-1,4-benzoquinone			
18.	Sterility	sterile	Sterile	sterile
19.	Bacterial endotoxins	not more than 0.33 USP Endotoxin Units/mg of propofol	not more than 1.65 I.U./ml	not more than 3.30 I.U./ml of emulsion
20.	Assay: Propofol	90.0 % – 110.0 %	95.0% - 105.0%	9.50 – 10.50 g/l

Decision 80th PRVC: The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided to defer the case for clarification on Globule size distribution, Impurities, Bacterial endotoxin limits and assay which are not comparable with BP & USP official monograph.

Firm reply:

#	**Specification**	**USP (acceptanc ecriteria)**	**BP (acceptance criteria)**	**B. Braun specification (acceptance criteria)**	**Technical and risk assessment**
1	Microscopic assessment	not directly stated	not directly stated	droplets ≤ 1 µm not less than 99 p.c. not more than 5 droplets > 2 to ≤ 10 µm per individual field no droplets > 10 µm	The in-house parameter microscopic assessment replaced the parameter globule size distribution. The mean particle size measurements are showing full compliance with the USP limit of ≤ 500 nm. The direct comparison of the results from Microscopic Assessment and from pFAT5 shows comparable results for both test methods. **Therefore the B. Braun method can be considered to be comparable to the United States Pharmacopeia (USP)/British Pharmacopoeia (BP) method** and makes sure that larger particles are
2	Globule size distribution	0.05 % v/v < 0.5 µm	≤ 5000 globules ≥ 2 µm/ml	not stated	

					identified**.**
3	Impurity [E] 3,3', 5,5'-tetrakis(1- methylethyl)biphenyl-4,4'-diol	≤ 0.5 %	0.25%	≤ 0.25%)	Comparable test methodology and limits are equal or tighter. **The B. Braun limits are chosen as equal, as they are specified according to British Pharmacopoeia (BP) limits.**
4	Impurity [J] 2,6-bis(1-methylethyl)-1,4-benzoquinone	≤0.5 %	0.1%	≤0.1%)	
5	Bacterial endotoxins	not more than 0.33 USP Endotoxin Units/mg of propofol	not more than 1.65 I.U./ml	not more than 0.33 Endotoxin Units/mg of propofol	Comparable unit and limit or a more widen limit. Theabsence of bacterial endotoxins by means of the LAL test is performed according to Ph. Eur. **The B. Braun Limit is in correspondence to the limit stated in the United States Pharmacopeia (USP) monograph.**
6	Assay: Propofol	90.0 % – 110.0 %	95.0 - 105.0%	95.0 - 105.0%	Comparable test methodology and limit is equal or tighter than pharmacopoeia reference. The limit is chosen according to EMA-Guideline "Specifications and Control Tests on the Finished Product" where it is stated that the maximum acceptable deviation in the active substance content of the finished products shall not exceed ± 5% at the time of manufacture. **Calculated into percentage, the B. Braun limit is in line to the limit of the BP monograph.**

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin.

Case No.13: <u>REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LTD, KARACHI FOR APPROVAL OF MANUFACTURER'S SPECIFICATIONS-EXELON 9MG (REG.NO.059068), 18MG (REG.NO.059069) & 27MG (REG.NO.074855)</u>

M/s Novartis Pharma (Pakistan) Ltd, 15-West Wharf, Dockyard Road, Karachi has submitted request with a fee of Rs.10,000/- for each product for approval of Manufacturer Specification for their registered products. Details are as under: -

059068 Exelon 4.6mg Transdermal Patch.
Each transdermal patch of 5cm^2 contains:-
Rivastigmine 9mg and releases rivastigmine at the rate of 4.6mg/24hours.

059069 Exelon 9.5mg Transdermal Patch. Each transdermal patch of 10cm^2 contains:-
Rivastigmine 18mg and releases rivastigmine at the rate of 9.5mg/24hours.

074855 Exelon Transdermal Patch.
Each transdermal patch of 15cm^2 contains:-
27mg Rivastigmine base, in vivo release rate of 13.3mg/24hours.

EXELON 4.6MG TRANSDERMAL PATCH (Reg. Number 059068)		
Parameters	**Novartis Specs (Innovator's Specification)**	**BP Specification**
Description: Appearance by visual examination	Circular 5 cm^2 transdermal drug delivery system, backing layer (beige), bi-layer adhesive matrix and an oversized rectangular overlapping release liner with dimples. Patch backing printed with "AMCX"	
Identification: Identity by TLC • Rivastigmine Identity by HPLC • Rivastigmine	 Corresponds to the reference Corresponds to the reference	The principal spot in the chromatogram obtained with solution (1) is similar in position and size to that in the chromatogram obtained with solution (2)
Properties Peel force Adhesion force	 Not more than 700 cN Not less than 1.41 N	
Performance Release rate by HPLC after • 2 hours • 4 hours • 7 hours	 31 - 73 % 42 - 80 % 55 - 87 %	
Impurities Degradation products, based on the declared content of Rivastigmine, by HPLC Specified • 226-90 • 213-95 • 802-95 • 017-05 Any unspecified Total degradation products	 Not more than 0.4 % Not more than 0.2 % Not more than 0.2 % Not more than 0.5 % Not more than 0.2 % Not more than 1.0 %	Related substances Impurity A Not more than 0.3 % Not more than 0.2 % Not more than 0.5 %
Microbial enumeration tests (Microbial Filtration method) • Total aerobic microbial count (TAMC) • Total combined yeasts /moulds count (TYMC) • Specified micro-organisms	 Not more than 10^2 CFU/G[F1] Not more than 10^1 CFU/g [F1] Absence of *Pseudomonas aeruginosa* in 1 system Absence of *Staphylococcus aureus* in 1 system [F1]	

Assay Uniformity of dosage units by content uniformity by HPLC. • Rivastigmine	Meets the requirements of Ph. Eur., USP and JP (release)	Comply with the requirements stated under uniformity of content, Appendix XII C3, Test C, with respect to the individual content of each dosage unit and using the following method of analysis. TEST C The preparation complies with the test if the average
Assay by HPLC • Rivastigmine	90.0 % - 110.0 % of the declared content	90.0 to 110.0% of the stated amount.
Assay by HPLC • D, L-α-tocopherol	80.0 - 110.0 % of the declared Content	
EXELON 9.5MG TRANSDERMAL PATCH (Reg. Number 059069		
Parameters	**Novartis Specs (Innovator's Specification)**	**BP Specification**
Description: Appearance by visual examination	Circular 10 cm^2 transdermal drug delivery system, backing layer (beige), bi-layer adhesive matrix and an oversized rectangular overlapping release liner with dimples. Patch backing printed with "BHDI"	
Identification: Identity by TLC • Rivastigmine Identity by HPLC • Rivastigmine	 Corresponds to the reference Corresponds to the reference	The principal spot in the chromatogram obtained with solution (1) is similar in position and size to that in the chromatogram obtained with solution (2)
Properties Peel force Adhesion force	 Not more than 1000 cN Not less than 2.00 N	
Performance Release rate by HPLC after • 2 hours • 4 hours • 7 hours	 31 - 73 % 42 - 80 % 55 - 87 %	
Impurities Degradation products, based on the declared content of Rivastigmine, by HPLC Specified • 226-90 • 213-95 • 802-95 • 017-05 Any unspecified Total degradation products	 Not more than 0.4 % Not more than 0.2 % Not more than 0.2 % Not more than 0.5 % Not more than 0.2 % Not more than 1.0 %	 Related substances Impurity A Not more than 0.3 % Not more than 0.2 % Not more than 0.5 %
Microbial enumeration tests (Microbial Filtration method) • Total aerobic microbial count (TAMC) • Total combined yeasts /moulds count (TYMC)	 Not more than 10^2 CFU/G[F1] Not more than 10^1 CFU/g [F1]	

• Specified micro-organisms	Absence of *Pseudomonas aeruginosa* in 1 system [F1] Absence of *Staphylococcus aureus* in 1 system [F1]	
Assay Uniformity of dosage units by content uniformity by HPLC • Rivastigmine	Meets the requirements of Ph. Eur., USP and JP	Comply with the requirements stated under uniformity of content, Appendix XII C3, Test C, with respect to the individual content of each dosage unit and using the following method of analysis. TEST C The preparation complies with the test if the average
Assay by HPLC • Rivastigmine	90.0 % - 110.0 % of the declared content	90.0 to 110.0% of the stated amount.
Assay by HPLC • D, L-α-tocopherol	80.0 - 110.0 % of the declared Content	
EXELON 13.3MG TRANSDERMAL PATCH (Reg. Number 074855)		
Parameters	**Novartis Specs (Innovator's Specification)**	**BP Specification**
Description: Appearance by visual examination	Circular 15 cm^2 transdermal drug delivery system, backing layer (beige), bi-layer adhesive matrix and an oversized rectangular overlapping release liner with dimples. Patch backing printed with "CNFU"	
Identification: Identity by TLC • Rivastigmine Identity by HPLC • Rivastigmine	 Corresponds to the reference Corresponds to the reference	The principal spot in the chromatogram obtained with solution (1) is similar in position and size to that in the chromatogram obtained with solution (2)
Properties Peel force Adhesion force	 Not more than 1200 cN Not less than 2.50 N	
Performance Release rate by HPLC after • 2 hours • 4 hours • 7 hours	 31 - 73 % 42 - 80 % 55 - 87 %	
Impurities Degradation products, based on the declared content of Rivastigmine, by HPLC Specified • 226-90 • 213-95 • 802-95 • 017-05 Unspecified, each Total degradation products	 Not more than 0.4 % Not more than 0.2 % Not more than 0.2 % Not more than 0.5 % Not more than 0.2 % Not more than 1.0 %	Related substances Impurity A Not more than 0.3 % Not more than 0.2 % Not more than 0.5 %

Microbial enumeration tests (Microbial Filtration method) • Total aerobic microbial count (TAMC) • Total combined yeasts /moulds count (TYMC) • Specified micro-organisms	Not more than 10^2 CFU/G[F1] Not more than 10^1 CFU/g [F1] Absence of *Pseudomonas aeruginosa* in 1 system [F1] Absence of *Staphylococcus aureus* in 1 system [F1]	
Assay Uniformity of dosage units by content uniformity by HPLC. • Rivastigmine	Meets the requirements of Ph. Eur., USP and JP	Comply with the requirements stated under uniformity of content, Appendix XII C3, Test C, with respect to the individual content of each dosage unit and using the following method of analysis. TEST C The preparation complies with the test if the average
Assay by HPLC • Rivastigmine	90.0 % - 110.0 % of the declared content	90.0 to 110.0% of the stated amount.
Assay by HPLC • D,L-α-tocopherol	80.0 - 110.0 % of the declared Content	

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin.

Case No.14: **REQUEST OF M/S WYETH PAKISTAN LTD, KARACHI. FOR APPROVAL OF MANUFACTURER SPECIFICATIONS – DBL CISPLATIN INJECTION 50MG/50ML (REG.NO.114194) & DBL CISPLATIN INJECTION 100MG/100ML (REG.NO.114195).**

M/s Wyeth Pakistan Limited, Room No.2&3, PGS Admin Block, 1st Floor, Karachi has submitted request with a fee of Rs.10000/- for each product for approval of Manufacturer Specification for their registered products. Details are as under: -

1. 114194 DBL Cisplatin Injection 50mg/50ml
   Each ml contains:
   Cisplatin 1mg
   (USP Specification)

2. 114195 DBL Cisplatin Injection 100mg/100ml
   Each ml contains:
   Cisplatin 1mg
   (USP Specification)

Sr.	Test Parameter	Manufacturer specifications	USP Specifications	BP Specifications
01	Description	A clear, colourless to pale yellow solution, free from visible particulates	N/A	A clear, colourless to pale yellow solution

02	Identification - HPLC	HPLC retention time of sample concordant with that of reference standard	N/A	In the Assay, the chromatogram obtained with the sample solution shows the peak at the same retention time as the principal peak in the chromatogram obtained with the standard solution.
03	Identification - UV	Exhibits a maximum at 300 nm	N/A	The light absorption in the range 230 to 350nm exhibits a maximum at 300 nm
04	pH	3.5 – 6.5	N/A	3.5 – 6.5
05	Assay	90.0 % - 105.0%	N/A	90.0 % - 105.0%
06	Related Substances-Transplatin	NMT 2.0%	N/A	NMT 2.0%
07	Related Substances - TCAP	NMT 3.0%	N/A	NMT 3.0%
08	Related Substances – Individual Unspecified Impurities	NMT 0.2%	N/A	NMT 0.2%
09	Related Substances – Total Unspecified Impurities	NMT 1.0%	N/A	NMT 1.0%
10	Extractable Volume	NLT 50 mL NLT 100 mL	N/A	NLT 50 mL NLT 100 mL
11	Particulate Matter	≥ 10 µm NMT 6000/ container ≥ 25 µm NMT 600/ container	N/A	N/A
12	Sterility	Complies with test	N/A	N/A
13	Bacterial Endotoxins	NMT 1.0 EU/mg	NMT 1.0 EU/mg	N/A

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

Case No.15: <u>REQUEST OF M/S BAYER PAKISTAN PVT. LTD. FOR APPROVAL OF INNOVATOR'S/ MANUFACTURER SPECIFICATIONS-YAZ TABLETS (REG. NO.059087).</u>

Subject case considered in 105th PRVC as under: -

M/s Bayer Pakistan (Pvt) Limited, Korangi Industrial Area, Plot No. 23, Sector No.22, Karachi has submitted request with a fee of Rs.10,000/- for each product for approval of Manufacturer Specification for their registered products. Details are as under: -

1. Yaz Tablet
   Each film coated tablet contains
   Drospirenone…3.0mg
   Ethinylestradiol…0.02mg

Sr.#	Test Parameters	Bayer's/Innovator's Specification	USP Specification

1	Appearance	Light pink round, biconvex	___
2	Markings tablet on one side	"DS" in a regular hexagon	___
	Markings tablet on other side	without	___
3	Identity of drospirenone (HPTLC)	conforms to detection 1 or detection 2	___
	Identity of ethinylestradiol (HPTLC)	conforms to detection 1 or detection 2	___
	Identity of drospirenone (HPLC)	corresponding retention time of sample and reference (difference ≤ 2 %)	corresponding retention time of sample and reference
	Identity of ethinylestradiol (HPLC)	corresponding retention time of sample and reference (difference ≤ 2 %)	corresponding retention time of sample and reference
	Identity of β-cyclodextrin (HPLTC)	corresponding R_f-value of the assigned spot of sample and principle spot of reference (difference ≤ 10 %)	___
	Identity of titanium dioxide	orange to orange-red solution	___
	Identity of ferric oxide	fine greenish blue to blue precipitate	___
4	iso-Compound	max. 0.2 %	NMT 0.3 %
	Any other	max. 0.3 %	NMT 0.5 %
	Total	max. 0.8 %	NMT 1.0 %
	6α-Hydroxy ethinylestradiol	max. 0.3 %	NMT 0.8 %
	6β-Hydroxy ethinylestradiol	max. 0.3 %	NMT 0.8 %
	Δ9(11)-Ethinylestradiol	max. 1.0 %	NMT 1.0 %
	6-keto-Ethinylestradiol	max. 0.5 %	NMT 0.8 %
	Any other	max. 0.5 %	NMT 0.5 %
	Total	max. 2 %	NMT 2.5 %
6	Dissolution of drospirenone Dissolution after 30 minutes Stage testing according Ph. Eur., USP, JP	Q=85 %	NLT 85 % (Q)
	Dissolution of ethinylestradiol Dissolution after 30 minutes Stage testing according Ph. Eur., USP, JP	Q=85 %	NLT 75 % (Q)
7	Uniformity of dosage units - content uniformity of drospirenone Stage testing according Ph. Eur., USP, JP	acceptance value max. 15.0 %	Meet the requirement
	Uniformity of dosage units - content uniformity of ethinylestradiol Stage testing according Ph. Eur., USP, JP	acceptance value max. 15.0 %	Meet the requirement

8	Assay of drospirenone (related to labeled claim)	95.0-105.0 %	90.0-110.0 %
	Assay of ethinylestradiol (related to labeled claim)	93.0-105.0 %	90.0-110.0 %
9	Total aerobic microbial count (TAMC)	max. 10^3 CFU/g	
	Total combined yeast/mould count (TYMC)	max. 10^2 CFU/g	
	Escherichia coli	absence in 1 g	

Manufacturer specifications approved in 105th PRVC meeting before the issuance of letter firm apply for changes in specification without fee for above product.

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin.

Case No.16: <u>REQUEST OF M/S SANOFI-AVENTIS PAKISTAN LIMITED, KARACHI FOR APPROVAL OF INNOVATOR'S/ MANUFACTURER SPECIFICATIONS-XATRAL LP 10MG TABLETS (REG.NO.044892).</u>

Subject case considered and discussed in 89th PRVC as per following details: -

The firm has submitted request for Manufacturer Specifications with a fee of Rs.10,000/- for Product Xatral LP 10mg Tablets (Reg No. 044892).

1. Xatral LP 10mg Tablets
   Each Tablet Contains:-
   Alfuzosin Hydrochloride 10mg.

Sr. No	Test	Innovator's specifications	USP Specifications	BP Specifications
1	**CHARACTERS**	Round, biconcave three-layer tablets: one white layer between two yellow layers	Not described	Not described
2	**IDENTIFICATIONS**			
	Alfuzosin			
	-by LC	Complies with reference chromatogram	Complies with reference chromatogram	Not described
	-by IR	Complies with reference spectrum	Complies with reference spectrum	Complies with reference spectrum
	Yellow ferric oxide	Positive reaction	Not described	Not described
3	**TESTS**			
	Uniformity of mass	Complies[c] (Ph. Eur. 2.9.5) ≤ 1.0%; ≤ 2.0%	Complies (UDU <905>)	Not described
	Friability		Not described	Not described
	Dissolution			Not described
	- Level L_1: 6 tablets	10-20% at 1 h	10-20% at 1 h	
	each tablet within:	40-55% at 6 h	40-55% at 6 h	
		65-85% at 12 h	65-85% at 12 h	
		≥85% at 20 h	NLT 85% at 20 h	

If one or more tablet(s) lie(s) outside the L_1 limits, then test a further 6 tablets

Level L_2: 6 more tablets

Average for 12 tablets and each tablet within:	Complies with level L_1	Complies with level L_1	
	8-22% at 1 h 35-60% at 6 h 60-90% at 12 h ≥80% at 20 h	9-22% at 1 h 36-61% at 6 h 59-94% at 12 h NLT 77% at 20 h	

If not more than 2 tablets lie outside the L_2 limits, then test a further 12 tablets

- Level L_3: 12 more tablets

Average for 24 tablets NMT 2 tablets outside L_2 limits	Complies with level L_1	Complies with level L_1	
and each tablet within:	NMT 2 tablets outside L^2 limits	NMT 2 tablets outside L^2 limits	
	8-22% at 1 h 35-65% at 6 h ≥60% at 12 h ≥80% at 20 h	8-24% at 1 h 32-66% at 6 h 52-102% at 12 h NLT68% at 20 h	

4	**Degradation products by LC**	≤ 0.5%	≤ 0.40%	≤ 0.5%
	- Impurity IV (D or Deacylated alfuzosin)	≤ 0.5%	≤ 0.30%	≤ 0.5%
	- Impurity VI (E or N-Formyl analog)	≤ 0.2%		≤ 0.2%
	- Unspecified (each)	≤ 1.0%	≤ 0.20%	≤ 1.0%
	- Total		≤ 0.80%	
5	**Ethanol by GC**	≤ 1.0%	Not described	Not described
6	**Microbiological quality**		Not described	Not described
	Microbial enumeration tests			
	- Total aerobic microbial count	≤ 10^3 CFU/g		
	- Total combined yeasts / moulds count	≤ 10^2 CFU/g		
	Specified micro-organisms			
	- *Escherichia coli*	Absence/1 g		
7	**Assay**			
	Alfuzosin HCl by LC	95.0 to 105.0%	90.0 to 110.0%	95.0 to 105.0%

Decision 89th PRVC:

The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided to defer for clarification of how dissolution and degradation of products are comparable with pharmacopeial specifications.

Firm reply:

Dissolution test are comparable with USP monograph while degradation products test is comparable with USP & BP Monograph both.

Decision 117th PRVC:

Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

Case No.17: <u>REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR GRANT OF INNOVATOR SPECIFICATIONS OF JANUVIA TABLETS.</u>

M/s Searle Pakistan Limited, Section E, 2nd Floor, One IBL Centre, Plot No. 1, Block 7&8, D.M.C.H.S., Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi has requested for grant of Innovator specifications of already registered drug with a fee of Rs.10,000/- as per following details;

059077 Januvia Tablets.
Each tablet contains:-
Sitagliptin phosphate monohydrate,
equivalent to 100mg sitagliptin

Sr.#	Test Parameters	USP specifications	Manufacturer Specifications
1.	Identification by NIR		The presence of Sitagliptin Phosphate is confirmed if the sample spectrum passes the criterion set forth in the library validation.
2.	Identification by UV	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay	
3.	Identification by RT (HPLC)	The retention time of the major peak of the sample solution corresponds to that of standard solution, as obtained in the Assay	
4.	Assay by **NIR† at release** and HPLC at shelf-life	95.0%–105.0% of label amount	95.0%–105.0% of label claim
5.	Impurities by HPLC	Sitagliptin acid – NMT 0.2% Fumarate adduct (if present) – NMT 0.2% Sitagliptin triazecine analog – NMT 0.2% Sitagliptin styrylacetyl analog – NMT 0.2% Sitagliptin phenyl-crotonyl analog– NMT 0.2% Any other individual impurity– NMT 0.2% Total impurities– NMT 0.6%	- - - - - Single Unspecified ≤ 0.2% (Shelf-life) Total Degradates ≤ 0.2% (Shelf-life)
6.	Uniformity of Dosage Units <905>	Meet <905> requirement	85.0-115.0% of label claim with ≤ c tablets outside criteria† (N ≥ 100 samples, c= f {N})
7.	Disintegration <701>	≤ 5 minutes	≤ 5 minutes

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

Case No.18: <u>REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR GSK SPECIFICATIONS OF REGISTERED PRODUCTS).</u>

The firm has submitted request for update in specification with a fee of Rs.10,000/- each for the following registered products: -

1. 043090 Duac Gel.
Contains:-
Clindamycin Phosphate 1.28%W/W.
Hydrous Benzoyl Peroxide 6.67%W/W.
(Anti Acne Preparation)..

Sr.#	Test parameter		Manufacturer specification	BP Specification
1.	Description	White to slightly yellow homogenous gel	N/A	
2.	Benzoyl Peroxide Identification		Rf value obtained for Benzoyl Peroxide in the sample and standard are similar	The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2)
3.	Clindamycin Phosphate Identification	First Identification by HPLC	Retention time for Clindamycin Phosphate in sample and standard are similar	The chromatogram obtained with solution (!) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2)
4.		Second Identification by TLC	The principal spot in chromatogram obtained with the full test solution is similar in position, color and size to the principal spot of the reference solution A and not present in the intermediate test solution	The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2)
5.	Clindamycin Phosphate Related	Clindamycin Phosphate Sulphoxide 1 as Clindamycin	≤ 0.02 %w/w	< 6 %

	Impurities as Clindamycin	Clindamycin Phosphate Sulphoxide 2 as Clindamycin	≤ 0.02 %w/w	< 2 %
		"Clindamycin Sulphoxide (CS2) as Clindamycin Impurity known as Clindamycin Sulphoxide 2 (CS2) as Clindamycin in both Australia & New Zealand"	≤ 0.02 %w/w	< 9 %
		Individual Unspecified Clindamycin Phosphate Related Substances as Clindamycin	No single substance is greater than 0.02 %w/w	< 15 %
		Clindamycin Phosphate Total Related Substances as Clindamycin	≤ 0.05 %w/w	< 1 %
10.	Benzoyl Peroxide Related Impurities	Benzoic Acid content	≤ 0.15 %w/w	< 5 %
		Unspecified degradation products related to benzoyl peroxide	No single substance is greater than 0.01 %w/w	< 0.2 %
		Total degradation products related to benzoyl peroxide excluding benzoic acid	≤ 0.10 %w/w	< 2 %
13.	Particle Size		Not less than 80% of particles are not more than 60µm	N/A
14.	Penetrometry		15.0 - 35.0 mm	N/A
15.	pH		4.0 - 5.5	N/A
16.	Benzoyl Peroxide content %w/w		4.75 - 5.25 %w/w (95%-105%)	90.0 to 110.0%
17.	"Clindamycin Phosphate (as Clindamycin)" Assay test		0.97 - 1.07 %w/w (97%-107%)	92.0 to 107.0%
18.	Microbiological Examination	Total Aerobic Microbial Count cfu/g	≤102 cfu/g interpreted as ≤ 200 cfu	N/A
		Total Yeasts and Mould Count cfu/g	≤101 cfu/g interpreted as ≤ 20 cfu	N/A

Staphylococcus Aureus	Absent in 1g	N/A
Pseudomonas Aeruginosa	Absent in 1g	N/A

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

2. 014918 Lamictal Tablets 25mg.
Each tablet contains
Lamotrigine 25mg.

Sr.	Test Parameter	Manufacturer specifications	USP Specifications	BP Specifications
1.	Characteristics	Pale yellowish brown, multifaceted, superelliptical, unscored tablet, branded 'GSEC7' on one side, with '25' on the reverse	N/A	N/A
2.	Identity Lamotrigine by UV scan	Complies with test	The spectra of the *Standard solution* and *Sample solution* exhibit maxima and minima at the same wavelengths.	N/A
	Identity Lamotrigine by TLC	Complies with test	N/A	The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).
	Identity Lamotrigine by HPLC	N/A	The retention time of the lamotrigine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.	In the Assay, the chromatogram obtained with solution (1) shows a principal peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).
3.	Lamotrigine assay by UV (% label strength)	95.0 - 105.0 %	N/A	N/A

	Lamotrigine assay by UV (mg/tablet)	23.75 – 26.25 mg/tablet	N/A	N/A
4.	Lamotrigine assay by HPLC	N/A	90.0% – 110.0%	95.0 to 105.0% of the stated amount.
5.	Uniformity of Dosage Units	Complies with Ph.Eur.	Meet the requirements	N/A
6.	Dissolution	Complies with Ph.Eur. Q=75% at 30 minutes	NLT 80% (*Q*) of the labeled amount of lamotrigine is dissolved after 30 min	The amount of Lamotrigine released is not less than 75% (Q) of the stated amount after 45 min
7.	Identification of Pigment (not routinely tested)	N/A	N/A	N/A
8.	Microbial Limits (not routinely tested): Total aerobic count Total yeast and mould count *Escherichia coli*	N/A	N/A	N/A
9.	Related substances	Each related substance: not more than 0.3 % w/w Total related substances: not more than 0.5 % w/w	Organic impurities: - Lamotrigine related compound B[a]: not more than 0.2% - Lamotrigine related compound C[b]: not more than 0.5% - Any individual unspecified degradation impurity: not more than 0.2% -Total impurities: not more than 0.75% <u>Note:</u> [a] 2,3-Dichlorobenzoic acid. [b] 3-Amino-6-(2,3-dichlorophenyl)-1,2,4-triazin-5(4*H*)-one.	In the chromatogram obtained with solution (1) : - the area of the peak corresponding to **impurity A** is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%); - the area of **any other secondary peak** is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%); - the sum of the areas of **all the secondary peaks** is not greater than 2.5 times the area of the

				principal peak in the chromatogram obtained with solution (2) (0.5%). Disregard any peak with an area less than 0.5 of the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.
Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin.

3. 014919 Lamictal Tablets 50mg.
Each tablet contains
Lamotrigine 50mg.

Sr.	Test Parameter	Manufacturer specifications	USP Specifications	BP Specifications
1.	Characteristics	Pale yellowish brown, multifaceted, superelliptical, unscored tablet, branded 'GSEE1' on one side, with '50' on the reverse	N/A	N/A
2.	Identity Lamotrigine by UV scan	Complies with test	The spectra of the *Standard solution* and *Sample solution* exhibit maxima and minima at the same wavelengths.	N/A
	Identity Lamotrigine by TLC	Complies with test	N/A	The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).
	Identity Lamotrigine by HPLC	N/A	The retention time of the lamotrigine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.	In the Assay, the chromatogram obtained with solution (1) shows a principal peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).
3.	Lamotrigine assay by UV (% label strength)	95.0 - 105.0 %	N/A	N/A
	Lamotrigine assay by UV (mg/tablet)	47.5 – 52.5 mg/tablet	N/A	N/A

4.	Lamotrigine assay by HPLC	N/A	90.0% – 110.0%	95.0 to 105.0% of the stated amount.
5.	Uniformity of Dosage Units	Complies with Ph.Eur.	Meet the requirements	N/A
6.	Dissolution	Complies with Ph.Eur. Q=75% at 30 minutes	NLT 80% (*Q*) of the labeled amount of lamotrigine is dissolved after 30 min	The amount of Lamotrigine released is not less than 75% (Q) of the stated amount after 45 min
7.	Identification of Pigment (not routinely tested)	N/A	N/A	N/A
8.	Microbial Limits (not routinely tested): Total aerobic count Total yeast and mould count *Escherichia coli*	N/A	N/A	N/A
9.	Related substances	Each related substance: not more than 0.3 % w/w Total related substances: not more than 0.5 % w/w	Organic impurities: - Lamotrigine related compound B[a]: not more than 0.2% - Lamotrigine related compound C[b]: not more than 0.5% - Any individual unspecified degradation impurity: not more than 0.2% -Total impurities: not more than 0.75% <u>Note:</u> [a] 2,3-Dichlorobenzoic acid. [b] 3-Amino-6-(2,3-dichlorophenyl)-1,2,4-triazin-5(4*H*)-one.	In the chromatogram obtained with solution (1) : - the area of the peak corresponding to **impurity A** is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%); - the area of **any other secondary peak** is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%); - the sum of the areas of **all the secondary peaks** is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%). Disregard any peak with an area less than 0.5 of the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

4. 014921 Lamictal Tablets 100mg.
Each tablet contains
Lamotrigine 100mg.

Sr.	Test Parameter	Manufacturer specifications	USP Specifications	BP Specifications
1.	Characteristics	Pale yellowish brown, multifaceted, superelliptical, unscored tablet. Branded 'GSEE5' on one side, with '100' on the reverse	N/A	N/A
2.	Identity Lamotrigine by UV scan	Complies with test	The spectra of the *Standard solution* and *Sample solution* exhibit maxima and minima at the same wavelengths.	N/A
	Identity Lamotrigine by TLC	Complies with test	N/A	The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).
	Identity Lamotrigine by HPLC	N/A	The retention time of the lamotrigine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.	In the Assay, the chromatogram obtained with solution (1) shows a principal peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).
3.	Lamotrigine assay by UV (% label strength)	95.0 - 105.0 %	N/A	N/A
	Lamotrigine assay by UV (mg/tablet)	95.0 - 105.0 mg/tablet	N/A	N/A
4.	Lamotrigine assay by HPLC	N/A	90.0% – 110.0%	95.0 to 105.0% of the stated amount.
5.	Uniformity of Dosage Units	Complies with Ph.Eur.	Meet the requirements	N/A
6.	Dissolution	Complies with Ph.Eur. Q=75% at 30 minutes	NLT 80% (*Q*) of the labeled amount of lamotrigine is dissolved after 30 min	The amount of Lamotrigine released is not less than 75% (Q) of the stated amount after 45 min
7.	Identification of Pigment (not routinely tested)	N/A	N/A	N/A

8.	Microbial Limits (not routinely tested): Total aerobic count Total yeast and mould count *Escherichia coli*	N/A	N/A	N/A
9.	Related substances	Each related substance: not more than 0.3 % w/w Total related substances: not more than 0.5 % w/w	Organic impurities: - Lamotrigine related compound B[a]: not more than 0.2% - Lamotrigine related compound C[b]: not more than 0.5% - Any individual unspecified degradation impurity: not more than 0.2% -Total impurities: not more than 0.75% <u>Note:</u> [a] 2,3-Dichlorobenzoic acid. [b] 3-Amino-6-(2,3-dichlorophenyl)-1,2,4-triazin-5(4*H*)-one.	In the chromatogram obtained with solution (1) : - the area of the peak corresponding to **impurity A** is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%); - the area of **any other secondary peak** is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%); - the sum of the areas of **all the secondary peaks** is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%). Disregard any peak with an area less than 0.5 of the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

5. 019501 Seroxat Tablets 20mg.
Each tablet contains
Paroxetine HCL 20mg.

Sr.	Test Parameter	Manufacturer specifications	USP Specifications	BP Specifications
1.	Description	White, film coated, oval shaped biconvex tablet, debossed with	N/A	N/A

		'20' on one side and a break bar on the other.		
2.	Identification of Paroxetine hydrochloride by HPLC	(identification by HPLC or TLC or UV)	The retention time of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.	In the Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the principal peak in the chromatogram obtained with solution (2).
	Identification of Paroxetine hydrochloride by TLC or UV	Passes test	N/A	**<u>UV:</u>** The *light absorption*, Appendix II B, in the range 230 to 350 nm of the final solution obtained in the Dissolution test exhibits a maximum at 294 nm.
	Identification of Paroxetine hydrochloride by IR	N/A	Meet the requirements	N/A
3.	Mean tablet weight	N/A	N/A	N/A
4.	Uniformity of dosage units	N/A	Meet the requirements	N/A
5.	Paroxetine content (Assay)	19.0 to 21.0 mg per tablet (95.0 to 105.0% of label claim).	90.0% – 110.0%	95.0 to 105.0% of the stated amount
6.	Dissolution (% Paroxetine released)	Complies with the requirements of USP where Q=75 at 30 minutes	NLT 80% (Q) of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$) is dissolved after 60 minutes	Q=75 % after 45 minutes
				the area of any peak corresponding to **impurity A** is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (**0.3%**);

7.	Related substances	BRL 35961 – not greater than 0.2 % Sesamol (Impurity I) – not greater than 0.2% Individual Unknown Impurity – not greater than 0.1% Total Unknown Impurities – not greater than 0.5%	N/A	the area of any peak corresponding to **impurity I** is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (**0.2%**);
				the area of **any other secondary peak** is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (**0.2%**);
				the sum of the areas of any other secondary peaks is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (**0.5%**)

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.
Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin.

6. 045684 Keppra Tablets 250mg.
Each film coated tablet contains
Levetiracetam 250mg.

7. 045685 Keppra Tablets 500mg.
Each film coated tablet contains
Levetiracetam 500mg..

Sr.	Test Parameter	Manufacturer Specification	USP Specification
1	Appearance	strength specific description	not included
2	Uniformity of dosage units	complies with EP	complies with the test
3	Water content	NMT 2.0%	not included
4	Dissolution	Q = 80 % after 30 min. Acceptance criteria USP, level 2	NLT 70% (Q) of the labeled amount of levetiracetam ($C_8H_{14}N_2O_2$) in 15 min for Tablets labeled to contain 250, 500, or 750 mg
5	Identification of Levetiracetam by achiral HPLC	Positive	Positive
6	Identification of Levetiracetam by TLC	Positive	not included
7	Identification of Levetiracetam by IR	not included	Positive
8	Identification of Titianium Dioxide	Positive (non routine test)	not included
9	Identification of colorants	Positive	not included
10	**Assay of Levetiracetam**	**95-105%**	**90-110%**

11	Degradation products: - Specified identified : 2-pyrrolidone-Nbutyric acid - Any unspecified - Total (specified and unspecified)	Not more than 0.50 % Not more than 0.10 % Not more than 0.80 %	NMT 0.3% NMT 0.1% NMT 0.6%
12	Microbiological quality	Complies with Ph. Eur	not included

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.
Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

Case No.19: **COMPLIANCE WITH PHARMACOPEIAL SPECIFICATION STANDARDIZATION OF FORMULATION (SEPTANEST WITH ADRENALINE 1/200000) (REG. NO. 114233).**

M/s Universal Dental (Pvt) Ltd, Opp. KE.Medical College Hostel, 17-Macleod Road, Lahore has submitted request for change of specification to Manufacturer's Specification with a fee of Rs.10,000/- for the following registered product: -

1. **114233** **Septanest with Adrenaline 1/200000**
Solution for Injection for Dental use
Each ml Contains:
Articaine Hydrochloride……40mg
Adrenaline (as adrenaline tartrate)….0.005mg

1.	**Test parameters**	**IN-HOUSE Specifications**	**USP Specifications**"
2.	Description Extractable volume pH Sub-visible particles Diameter ≥ 10 µm	Clear and colourless solution practically free from particles No cartridge < Nominal volume 4.0 to 5.5 ≤ 6000 per cartridge	Clear and colourless solution, free from visible particulate matter The volume is NLT the nominal volume of
3.	**IDENTIFICATIONS**		
	Articaine hydrochloride		
	. A. Thin Layer Chromatography	Complies	NA

	. B. HPLC: retention time	Complies	The retention times of the articaine peak from the Sample solution correspond to
	Adrenaline tartrate (Epinephrine)		
	. A. HPLC: retention time	Complies	The retention times of the epinephrine peak from the Sample solution
	. B. HPLC: redox potential	Complies	NA
	Sodium metabisulfite	Positive	NA
	Disodium edetate	Positive	NA
4.	**ASSAYS**		
	Articaine hydrochloride	3.80 to 4.20 g / 100 ml (95 – 105%)	95.0 % - 105.0 %
	Adrenaline tartrate (epinephrine) (expressed as base)	0.50 to 0.55 mg / 100 ml (100 – 110%)	90% - 115%
	Sodium chloride*	0.144 to 0.176 g / 100 ml	NA(b)
	Sodium metabisulfite Expressed in SO_2	35 to 50 mg / 100 ml 24 to 34 mg / 100 ml	NA(b)
	Disodium edetate	22 to 27 mg / 100 ml	NA(b)
5.	**DEGRADATION PRODUCTS**		
	Degradation products of Articaine Hydrochloride Articainic acid (Articaine related compound B) at RRT 0.6		
	. (reported if > 0.02 %)	≤ 0.5 %	≤ 0.5 %
	. Any other individual impurity (reported if > 0.03 %)	≤ 0.1 %	≤ 0.2 %
	. Total impurities (reported if > 0.05 %)	≤ 0.5 %	≤ 0.5 %
6.	Degradation products of Adrenaline tartrate		
	. Adrenaline sulfonic acids[1] at RRT 0.46 (Epinephrine Sulfonate) (reported if > 5.0 %)	≤ 10.0 % (0.4 µg/ml, as Adrenaline)	≤ 7.5 %
	. Sulfosulfanyl impurity[2] (specified impurity) (reported if > 1.1 %)	≤ 8 %	≤ 8 %

	. Any other individual impurity (reported if > 0.5 %)	≤ 1.0 %	≤ 1 %
	. Total impurities[4]	≤ 10 %	≤ 10 %
7.	**ENANTIOMERIC PURITY** . (S)-Adrenaline	- 	 Not provided in USP
8.	**BIOLOGICAL TESTS** Sterility Bacterial endotoxins	 Sterile < 0.7 IU/mg of Articaine HCl	 Sterile ≤ 0.7 USP endotoxin Unit/mg of Articaine HCl

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

Case No.20: <u>REQUEST OF M/S SANOFI-AVENTIS PAKISTAN LIMITED, KARACHI FOR SPECIFICAITN LIMIT OF WATER CONTENT TEST – TARGOCID 200MG INJECTION (REG.NO.019503).</u>

The firm has submitted request for manufacturer specification with a fee of Rs.10,000/- for Targocid 200mg Injection (Reg.No.019503).

1. 019503 Targocid 200mg Injection.
Each 3ml vial contains:
Teicoplanin…200mg.

Test Parameters	**Innovators Specifications**	**BP specifications**
Description	Spongy, ivory coloured homogenous mass	Not described
Description of reconstituted solution	Clear, yellow-dark yellow solution	Not described
pH (Reconstituted solution)	7.5 ± 0.3	6.0 to 8.0
Reconstitution time	NMT 240 sec	Not described
Water Content	NMT 3.0%	Not described
Composition of complex - Group A3 - Group A2	 ≤ 20% ≥ 75%	 not more than 17% not less than 78%
Related substances	≤ 5%	— any non-*teicoplanin*-like impurity: not more than 0.5% — total non-*teicoplanin*-like impurities: not more than 1.5% — Disregard any peak due to impurity A.
Microbiological activity - Lower fiducial limit - Upper fiducial limit	200,000 U/vial ≤ 115% (NMT 230,000 U/vial) ≥ 95% (NLT 190,000 U/vial)	 NMT 115% NLT 95%
Sterility	Complies	Sterile

Bacterial Endotoxins	< 0.3125 EU/mg	Not described
Particulate contamination: sub-visible particles	≥ 10µm: ≤ 6000 particles/vial ≥ 25µm: ≤ 600 particles/vial	Not described

Decision 117th PRVC:
Chairman Registration Board on recommendation of committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the case for submission of approvaed specifications in its country of origin

RRR Section

Case No: 1 Renewal applications submitted after due date but within prescribed time period under Rule 27 of Drug LR&A Rules 1976.

Sr. No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s Harrison Pharmaceuticals, 10 Km Lahore Road Sargodha.					
1.	050102	Anagix DS Tablet 500mg Each tablet contains: Mefenamic Acid….500mg (BP Specifications)	22.07.2008	Rs.10000/- dated 21.08.2013 Rs. 10000/- dated 21.12.2016 (Diff. fee of 2013) Rs. 20000/- dated 27.09.2018 Rs. 10000/- dated 16.09.2019 (diff fee for 2018) Rs. 15000/- dated 20.07.2023	Renewal is granted w.e.f. 22.07.2023 to 21.07.2028 Renewal letter shall be issued after submission of valid GMP certificate/ inspection report
2.	050103	Anagix Tablet 250mg Each tablet contains: Mefenamic Acid….250mg (BP Specifications)	22.07.2008	Rs.10000/- dated 21.08.2013 Rs. 10000/- dated 21.12.2016 (Diff. fee of 2013) Rs. 20000/- dated 27.09.2018 Rs. 10000/- dated 16.09.2019 (diff fee for 2018) Rs. 15000/- dated 20.07.2023	Renewal is granted w.e.f. 22.07.2023 to 21.07.2028 Renewal letter shall be issued after submission of valid GMP certificate/ inspection report
3.	050104	Harriprox 550mg Tablets Each tablet contains: Naproxen Sodium…550mg (BP Specifications)	22.07.2008	Rs.10000/- dated 21.08.2013 Rs. 10000/- dated 21.12.2016 (Diff. fee of 2013) Rs. 20000/- dated 27.09.2018 Rs. 10000/- dated 16.09.2019 (diff fee for 2018) Rs. 15000/- dated 20.07.2023	Renewal is granted w.e.f. 22.07.2023 to 21.07.2028 Renewal letter shall be issued after submission of valid GMP certificate/ inspection report

4.	050107	Diclokam-K Tablets 75mg Each tablet contains: Diclofenac Potassium…75mg (USP Specifications)	22.07.2008	Rs.10000/- dated 21.08.2013 Rs. 10000/- dated 21.12.2016 (Diff. fee of 2013) Rs. 20000/- dated 27.09.2018 Rs. 10000/- dated 16.09.2019 (diff fee for 2018) Rs. 15000/- dated 20.07.2023	Registration is already suspended vide DRAP letter No. 5-3/2022-Reg-II (M-317) (Misc) dated 01.06.2022.
5.	050108	T-Zine Tablets 10mg Each tablet contains: Cetirizine dihydrochloride…10 mg (USP Specifications)	22.07.2008	Rs.10000/- dated 21.08.2013 Rs. 10000/- dated 21.12.2016 (Diff. fee of 2013) Rs. 20000/- dated 27.09.2018 Rs. 10000/- dated 16.09.2019 (diff fee for 2018) Rs. 15000/- dated 20.07.2023	Renewal is granted w.e.f. 22.07.2023 to 21.07.2028 Renewal letter shall be issued after submission of valid GMP certificate/ inspection report

Shortcomings (F. No.3-1/2023 (Renewal) dated 27.11.2023)	**Reply**
a. One differential fee for year 2018 is still required. b. Latest GMP inspection report. c. Differential fee/ evidence of submission of fee for remaining product registered vide letter No. F.13-1/2008-Reg-II (M-212) dated 22.08.2008. d. Copy of BP monograph for Naproxen Sodium Tablets. e. Specifcations of Cetirizine hydrochloride tablets is available in reference pharmacopeia, clarification required on which specs you are authorizing the batch release (manufacturer or pharmacopeial).	a. The firm has submitted the evidence of submission of differential fee as recorded above. b. The firm has submitted copy of GMP report dated 08.11.2018 wherein the FID reported that condition of the firm was very pathetic regrading to documentation, QA, HVAC system, testing method, validation and calibration. The firm was directed to submit compliance report. c. The query is not responded by the firm. d. The firm has submitted copy of application dated 02.08.2022 for grant of BP Specifications for Harriprox 550mg Tablets e. The firm has submitted copy of application dated 02.08.2022 for grant of USP Specifications for T-Zine Tablets 10mg.

M/s Avant Pharmaceuticals (Pvt) Ltd. Plot No.M-28, Hub Industrial Trading Estate Hub- Pakistan

6.	092632	Utriaxone Injection 1g (IV) Each vial contains: Ceftriaxone as sodium…1g (USP Specifications) **Manufacturer**: M/s Mediate Pharmaceuticals Pvt Limited, Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi	09.10.2018	Dy. No. 28435 dated 08.12.2023 Rs. 15000/-	Renewal is granted w.e.f. 09.10.2023 to 08.10.2028
7.	092633	Utriaxone Injection 500mg (IV) Each vial contains: Ceftriaxone as sodium…500mg (USP Specifications)	09.10.2018	Dy. No. 28437 dated 08.12.2023 Rs. 15000/-	Renewal is granted w.e.f. 09.10.2023 to 08.10.2028

		Manufacturer: M/s Mediate Pharmaceuticals Pvt Limited, Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi			
Shortcomings (F. No. 3-1/2023-RRR dated 11.12.2023)					
i. Copy of contract agreement under prevailing contract manufacturing policy. ii. Differential fee (Rs. 285000/- each product) is required as renewal application due date was 08.10.2023 however the it was submitted on 08.12.2023 i.e. after 60 days but with one year under SRO 1005(I)/2017. iii. Details of last batches manufactured. iv. Latest GMP inspection report of M/s Mediate Pharmaceuticals Pvt Limited, Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi.				The firm has submitted the copy of contract agreement. The firm has submitted 285000/- (57234146) and 285000/- (55952165) for Utriaxone Injection 1g and 500mg Details of last batches submitted. GMP certificate issued by DRAP Karachi dated 18.05.2023 is submitted.	
M/s. Uni-Tiech Pharmaceuticals Pvt Limited, Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi					
8.	050518	OMPETEC 20MG CAPSULE Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole…..20mg (Manufacturer Specifications) Source of pellets: M/s. Euroaisa Trans Continental India	27.08.2008	Rs.30000/- Dy No.25675 Dated 23.10.2023 & Rs.15000/- Dy No.29547 Dated 18.10.2022	
i. Notarized copy of submission of renewal application for year 2013 & 2018. ii. License/ Approval to manufacture pellets by the manufacturer i.e., M/s. Euroaisa Trans Continental India, issued by the regulatory authority of country of origin. iii. GMP certificate issued by issued by the regulatory authority of country of origin. iv. Stability data of pellets from manufacturer i.e. M/s. Euroaisa Trans Continental India.					
9.	050516	UNIGASTIC 0.3MG INJECTION Each ml contains: Buprenorphine (as HCl) …0.3mg (Manufacturer Specifications)	27.08.2008	Dy No.25674 Dated 23.10.2023 Rs.30000/- Rs.10000/- Dated 15.07.2019 Rs.10000/- Dated 14.07.2014	
10.	050517	SOSETIECH 30MG INJECTION Each ml contains: Pentazocine (as Lactate) ….30mg (USP Specifications)	27.08.2008	Dy No.25674 Dated 23.10.2023 Rs.30000/- Rs.10000/- Dated 15.07.2019	

				Rs.10000/- Dated 14.07.2014	
i. Notarized copy of submission of renewal application for year 2013 & 2018. ii. Justification for submitting renewal applications on 14.07.2014 & 15.07.2019 (after the due date) iii. Copy of approval of section from Licensing Division for narcotic/ psychotropic drugs (liquid Injection). iv. Brief details of last batch manufactured.					
11.	053353	ALPRAZOLAM 1MG TABLETS Each tablet contains: Alprazolam…….1mg (BP Specifications)	15.12.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.10000/- dated 15.07.2019 & Rs.10000/- dated 14.07.2014	
i. Notarized copy of registration letter. ii. Notarized copy of submission of renewal application for year 2013 & 2018. iii. Justification for submitting renewal applications on 14.07.2014 & 15.07.2019 (after the due date) iv. Copy of approval of section from Licensing Division for narcotic/ psychotropic drugs (Tablet). v. Brief details of last batch manufactured.					
12.	047472	SNAGLIN 500MG DRY POWDER INJECTION Each vial contains Cefazolin as sodium…..500mg (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.15000/- dated: 28.11.2022	
13.	047473	SNAGLIN 1 DRY POWDER INJECTION Each vial contains: Cefazolin (as Sodium) …...1g (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.10000/- dated: 24.02.2020	
14.	047470	UNI-CEFTY 500MG DRY POWDER INJECTION Each vial contains: Cefoperazone (as Sodium) ……500mg (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.10000/- dated: 24.02.2020	
15.	047471	UNI-CEFTY 1G DRY POWDER INJECTION Each vial contains: Cefoperazone (as Sodium) ……1g (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.10000/- dated: 24.02.2020	

i. Notarized copy of registration letter is required as submitted copy bears no signatures of issuing authority. ii. Notarized copy of submission of renewal application for year 2013 & 2018. iii. Notarized copy of submission of renewal application for year 2013 & 2018. iv. Copy of approval of section from Licensing Division for Dry Powder Injection Cephalosporin. v. Brief details of last batch manufactured.					
16.	047474	UNI-PRIMA 500MG DRY POWDER INJECTION Each vial contains: Cefpirome (as Sulphate)..500mg (Antibiotic) (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- Rs.15000/- dated: 28.11.2022	
17.	047475	UNI-PRIMA 1G DRY POWDER INJECTION Each vial contains: Cefpirome (as Sulphate) …...1 g (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- 20000/- dated 23.01.2015	
i. Notarized copy of registration letter is required as submitted copy bears no signatures of issuing authority. ii. Notarized copy of submission of renewal application for year 2013 & 2018. iii. Notarized copy of submission of renewal application for year 2013 & 2018. iv. Copy of approval of section from Licensing Division for Dry Powder Injection Cephalosporin. v. Evidence of availability of formulation in RRA. vi. Copy of USP monograph for API & Finished Product Specifcations. vii. Brief details of last batch manufactured.					
18.	047476	SISOPIME 500MG DRY POWDER INJECTION Each vial contains: Cefepime HCl…...500mg (USP Specifications)	24.01.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- 15000/- dated 22.11.2022	
i. Notarized copy of registration letter is required as submitted copy bears no signatures. ii. Notarized copy of submission of renewal application for year 2013 & 2018. iii. Copy of approval of section from Licensing Division for Dry Powder Injection Cephalosporin. iv. Revision of label claim as per USP monograph. v. Brief details of last batch manufactured.					
19.	073760	NOR-NEX 250MG TABLET Each tablet contains: Naproxen (as sodium) ….250 mg (USP Specifications)	24.01.2013	Dy No.25674 dated 23.10.2023 Rs.30000/-	
i. Notarized copy of registration letter. ii. Clarification required that the renewal application submitted on 04.12.2017 bears different reg. No i.e., 048675) for Nor-Nex 250mg Tablet. iii. Evidence of submission of renewal for year 2018. iv. Copy of approval of section from Licensing Division for Dry Powder Injection Cephalosporin. v. Brief details of last batch manufactured.					
20.	053275	AMOXYCILLIN 250MG/5ML SUSPENSION Each 5ml contains: Amoxicillin as Trihydrate…...250mg	02.12.2008	Dy No.25674 dated 23.10.2023 Rs.30000/-	

		(BP Specifications)		15000/- dated 28.11.2022	
i. Notarized copy of registration letter is required. ii. Notarized copy of submission of renewal application for year 2013 & 2018. iii. Copy of approval of section from Licensing Division for Dry Powder Suspension (penicillin). iv. Brief details of last batch manufactured.					
21.	048659	DICFLAKE 50MG TABLET Each tablet contains: Diclofenac sodium….. 50 mg (BP Specifications)	15.07.2008	Dy No.25674 dated 23.10.2023 Rs.30000/- 15000/- dated 22.11.2022	
22.	048675	NOR-NEX 500MG TABLET Each tablet contains: Naproxen (as sodium)……500 mg (USP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
23.	048674	UNIMETHER 80MG/ML INJECTION Each ml contains: Artemether….80mg (Manufacturer Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
24.	048657	U- GLIM 1MG TABLET Each Tablet contains: Glimepiride….1mg (USP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
25.	048660	VICOSAR 80MG TABLET Each tablet contains: Valsartan….80mg (BP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
26.	048661	VICOSAR 160MG TABLET Each tablet contains: Valsartan….160mg (BP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
27.	048667	UNIFLUR 100MG TABLET Each tablet contains: Flurbiprofen…100mg (BP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	

28.	048672	UNICOBAL 500MCG INJECTION Each ml contains Mecobalamin…500 mcg (Manufacturer Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
29.	048673	UNICOBAL 500MCG TABLET Each tablet contains: Mecobalamin…500mcg (Manufacturer Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
30.	048668	Unistrip Each lozenge contains: Dybenal…….1.2mg, Amylmetacresol...0.6mg (BP Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
31.	048670	UNIMOX 400MG TABLET Each Tablet contains: Moxifloxacin…400mg (Manufacturer Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
32.	048664	VITATECH 500MG TABLET Each chewable tablet contains: Vitamin C…...500mg (Manufacturer Specifications)	15.07.2008	Dy No. 25674 dated 23.10.2023 Rs.30000/- 15000/- dated 28.11.2022	
i. Notarized copy of submission of renewal application for year 2013 & 2018. ii. Brief details of last batch manufactured.					
Remarks: A letter was issued to the firm vide No. F.3-1/2023-RRR dated 15.12.2023 for the provision of above documents as mentioned against each. The firm on 26.12.2023 informed that *"our Compliance office Miss Rabia Dar is out of Pakistan in order to perform Umrah. We will assure you that we submit the required details of renewal application shortcomings after her arrival that is between 26th to 28th December, 2023"* The firm has not submitted reply yet.					
Decision: **Registration Board directed the firm to apply afresh for registration of above products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.**					
M/s. Medipak Ltd., 132, Industrial Estate Kot Lakhpat Lahore					
33.	052859	Leomax Tablet 10mg Each tablet contains: Leflunomide……10mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications.
Application and fee Rs, 10000/- for grant of USP Specs is submitted					

34.	052862	Leomax Tablets 100mg Each tablet contains: Leflunomide ……100mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications
Application and fee Rs, 10000/- for grant of USP Specs is submitted					
35.	052867	Ciprofena Tablets 500mg Each tablets contains: Ciprofloxacin HCl eq. to Ciprofloxacin…..500mg (USP Specifications)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028
36.	052869	Medipride Tablets 1mg Each tablets contains: Glimepiride…1mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications
Application and fee Rs, 10000/- for grant of USP Specs is submitted					
37.	052870	Agranil Tablets Each tablets contains: Clopidogrel Bisulphate eq. to Clopidogrel…75mg (USP Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028
38.	052873	Leovin Tablets 500mg Each tablets contains: Levofloxacin……500mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications
Application and fee Rs, 10000/- for grant of USP Specs is submitted					
39.	052875	Medipride Tablets 4mg Each tablets contains: Glimepiride…..4mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications
Application and fee Rs, 10000/- for grant of USP Specs is submitted					
40.	052876	Sarutan Plus Tablets Each tablets contains: Losartan Potassium eq. to losartan……...50mg Hydrochlorothiazide…..12.5mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications
Application and fee Rs, 10000/- for grant of USP Specs is submitted					

41.	052877	Ciprofena Tablets 250mg Each tablets contains: Ciprofloxacin HCl eq. to ciprofloxacin…250mg (USP Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028
42.	52868	Medipride Tablets 2mg Each tablets contains: Glimepiride…….2mg (Medipak's Specs)	26/11/2008	Rs.15000/- Dy.No.29952 29.12.2023 Rs. 15000/- dated 24.01.2024	Renewal is granted w.e.f 26.11.2023 to 25.11.2028 with USP Specifications

Application and fee Rs, 10000/- for grant of USP Specs is submitted

Shortcomings (F. No. 3-1/2023-RRR dated 04.01.2024)	**Reply**
i. Differential fee Rs. 15000/- each is required as renewal application is submitted after due date but within sixty days. ii. The products having "Medipak Specs" are included in the reference pharmacopeia, hence you are advised to submit the same as per PRV guidelines with requisite fee for consideration. iii. Description of all applied tablets whether film coated, uncoated etc., iv. Section approval letter issued by Licensing Division. v. Copy of latest GMP inspection report/ certificate.	The firm has submitted the differential fee Rs. 15000/- each. The firm has submitted 10000/- each fee for change of specifcations from Medipak Specs to USP The firm has submitted descriptions as per reference product and requested for standardization. GMP certificate submitted is not valid as of today. The firm copy of an application dated 18.01.2023 to DRAP Lahore for GMP inspection. Section approval letter indicating Tablet General issued vide Licensing Division Letter 1-46/85-Lic(Vol-III) dated 08.06.2021.

M/s. Ideal Pharma Industries,18-Km Ferozepur Road Lahore

43.	007602	Iodopyrin Tab Each tablet contains:- Aspirin……300mg, Paracetamol….75mg, Caffeine…..10mg,	28/12/1988	Rs.15000/- Dy.No.29969 29.12.2023	

Shortcomings (F. No. 3-1/2023-RRR dated 08.01.2024)	**Reply**
i. Differential fee Rs. 15000/- each is required as renewal application is submitted after due date but within sixty days. ii. Evidence of approval of formulation in RRA. iii. Valid copy of DML iv. Copies of section approval letter. v. Details of last batches manufactured. vi. Reference of finished product specifcations. vii. Post registration variations approvals (if any). viii. Latest GMP inspection report.	The firm has not responded yet.

Decision: Deferred for issuance of final reminder for shortcomings as mentioned above vide letter F. No. 3-1/2023-RRR dated 08.01.2024.

M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Plot No. A-127 SITE Super Highway Karachi.

44.	022529	Vitamin E Capsule Each capsule contains: Alphatocopheryl Acid Succinate…..400IU	23/11/1998	Rs.30000/- Dy.No.29957 29.12.2023	

		Imported in Bulk from M/s Amco Pharmaceuticals Inc., Canada and repacked locally			
45.	022530	Eplolina Gelcap Capsules Each capsule contains: Evening prime rose oil……..500mg (9.5% Gamma Linolenic Acid) Vitamin E…15IU M/s Amco Pharmaceuticals Inc., Canada and repacked locally	23/11/1998	Rs.30000/- Dy.No.29957 29.12.2023	

Shortcomings (F. No. 3-1/2023-RRR dated 08.01.2024)	**Reply**
i) Differential fee Rs. 30000/- each is required as renewal application is submitted after due date but within sixty days. ii) Notarized copy of complete registration letter. iii) Evidence of approval of formulation in RRA. iv) Legalized CoPP/ Free Sale Certificate and GMP Certificate of for Vitamin E Capsules & Eplolina Gelcap Capsules imported in bulk from M/s Amco Pharmaceuticals Inc., Canada. v) Copy of last import invoice along with the copy of DRAP clearance certificate and Certificate of analysis by the manufacturer. vi) Finished product specifcations along the latest issued certificate of analysis for batches released in market. vii) Post registration variations approvals (if any). viii) Latest GMP inspection report. ix) Copy of valid DML. x) Copy of section approval letters.	The firm has not submitted reply yet.

Decision: Deferred for issuance of final reminder for submission of shortcomings as mentioned above vide letter F. No. 3-1/2023-RRR dated 08.01.2024.

M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Plot No. A-127 SITE Super Highway Karachi.

46.	022526	Pizofen Syrup Each 5ml contains: Pizotifen (as hydrogen maleate)…….0.25mg	23/11/1998	Rs.15000/- Dy.No.29956 29.12.2023 **Rs. 15000/- dated 01.02.2024**	Renewal is granted w.e.f. 23.11.2023 to 22.11.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board
47.	022527	Pizofen Tablet Each tablet contains: Pizotifen (as hydrogen malate)…….0.5mg	23/11/1998	Rs.15000/- Dy.No.29956 29.12.2023 **Rs. 15000/- dated 01.02.2024**	Renewal is granted w.e.f. 23.11.2023 to 22.11.2028. The firm shall submit description of dosage form (film coated or uncoated etc.,) and reference of finished product specification with fee

					as per decision of 295th meeting of Registration Board
48.	022528	Pizofen V Syrup Each 5ml contains: Pizotifen (as hydrogen maleate) …….0.25mg Thiamine HCl……0.875mg Riboflavin 5 Phosphate Sodium……1.31mg Pyridoxine HCl….0.77mg, Nicotinamide….5.25mg	23/11/1998	Rs.15000/- Dy.No.29956 29.12.2023 **Rs. 15000/- dated 01.02.2024**	Deferred for submission of approval of formulation in RRA

Shortcomings (F. No. 3-1/2023-RRR dated 08.01.2024)	**Reply**
i. Differential fee Rs. 15000/- each is required as renewal application is submitted after due date but within sixty days. ii. Notarized copy of complete registration letter. iii. Evidence of approval of formulation in RRA. iv. Valid copy of DML v. Copies of section approval letter. vi. Details of last batches manufactured. vii. Reference of finished product specifcations. viii. Post registration variations approvals (if any). ix. Latest GMP inspection report.	The firm has submitted differential fee Rs. 15000/- each as recorded above. The firm has submitted notarized copy of letter but again didn't submit the page on which the name of registration holder is mentioned. The status is recorded above. Valid DML is not submitted but copy of application for renewal provided. Last batches details submitted. The firm submitted specifcations which are merely name of tests with limits and does not include the all quality tests which are required for a particular dosage form. GMP report dated 30.06.2021 by the area FID wherein GMP was rated satisfactory.

M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Plot No. A-127 SITE Super Highway Karachi.

49.	004338-EX	SALGICEF Suspension Each 5ml contains Cefixime Trihydrate eq. to Cefixime anhydrous…..100mg	25/11/2013	Rs.15000/- Dy.No.29958 29.12.2023	

Shortcomings (F. No. 3-1/2023-RRR dated 08.01.2024)	**Reply**
i. Differential fee Rs. 15000/- each is required as renewal application is submitted after due date but within sixty days. ii. Valid copy of DML iii. Copies of section approval letter. iv. Latest GMP inspection report.	The firm has not submitted reply yet.

Decision: Deferred for issuance of final reminder for submission of shortcomings as mentioned above vide letter F. No. 3-1/2023-RRR dated 08.01.2024.

M/s. Albert Pharma (Pvt) Ltd Plot No.127, Sundar Industrial Estate, Raiwind Road, Lahore

50.	086325	Mesodim 200mg Capsules Each capsule contains: Mebeverine hydrochloride sustained release pellets eq. to Mebeverine hydrochloride……200mg	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned

		As per *Innovator's Specification **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.			Post Registration Variation Section.
51.	086324	Sprain 60mg Capsules Each capsule contains: Enteric coated pellets of Duloxetine (as hydrochloride) ….60mg (USP Specifications) **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
52.	086323	Sprain 20mg Capsules Each capsule contains: Enteric coated pellets of Duloxetine (as hydrochloride) ….20mg (USP Specifications) **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
53.	086322	Esobert 40mg Capsule Each capsule contains: Esomeprazole (as magnesium trihydrate enteric coated pellets) eq. to esomeprazole……40mg (USP Specification) **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
54.	086321	Esobert 20mg Capsule Each capsule contains; Esomeprazole (as magnesium trihydrate enteric coated pellets) eq. to Esomeprazole……20mg (USP Specification)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned

		Source of pellets: M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.			Post Registration Variation Section.
55.	086320	Exocid 40mg Capsule Each capsule contains: Omeprazole (enteric coated pellets) …40mg (USP Specification) **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
56.	086319	Exocid 20mg Capsule Each capsule contains Omeprazole (enteric coated pellets) ……20mg (USP Specification) **Source of pellets:** M/s Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle Kahuta Road, Islamabad.	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
57.	086318	A-Calm 20mg Tablet Each film coated tablet contains: Escitalopram (as oxalate) …...20mg (USP Specifications)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
58.	086317	A-Calm 10mg Tablet Each film coated tablet contains: Escitalopram (as oxalate) ……10mg (USP Specifications)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
59.	086316	A-Calm 5mg Tablet Each film coated tablet contains: Escitalopram (as oxalate) ……...5mg (USP Specifications)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.

60.	086315	Mesodim 135mg Tablet Each film coated tablet contains: Mebeverine Hydrochloride….135mg (BP Specifications)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
61.	086314	Baliptic 150 mg Capsule Each capsule contains: Pregabalin…150mg (BP Specifications)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
62.	086313	Baliptic 100 mg Capsule Each capsule contains: Pregabalin…100mg (As per *Innovator's Specification)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
63.	086312	Baliptic 75 mg Capsule Each capsule contains: Pregabalin….75mg (As per *Innovator's Specification)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.
64.	086311	Baliptic 50 mg Capsule Each capsule contains: Pregabalin….50mg (As per *Innovator's Specification)	20.12.2017	Rs.15000/- 21.12.2022 & Rs.15000/- Dy.No.27404-R&I Dated 21.11.2023	Renewal is granted w.e.f. 20.12.2022 to 19.12.2027.

Shortcomings (F. No. 3-1/2023-RRR dated 15.01.2024)	**Reply**
The tittle of manufacturer has been changed from "M/s Vision Pharmaceuticals" to Vision Pharmaceuticals Pvt Limited vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018. Approval change of title of manufacturer for products containing pellets need to be submitted, otherwise submit the application with requisite fee for consideration of the Registration Board. Latest GMP inspection report/ GMP certificate issued by DRAP Lahore. Brief details of last batches manufactured with copies of certificate of analysis. Copy of valid DML and section approval letter.	The firm has submitted copy of approval of title issued by Licensing Division, however approval in respect of title of manufacturer for products containing pellets is not submitted. GMP inspection report dated 20.05.2019 is submitted rayed as GMP compliant. The firm has submitted the details of batches manufactured. The firm has submitted the copy of panel letter for inspection of DML dated 02.12.2022.

M/s. Danas Pharmaceuticals (Pvt) Ltd.312 Industrial Triangle Kahuta Road, Islamabad					
65.	052675	SAVERIL TABLETS 100MG	21/10/2008	Rs.30000/- Dy.No.26837	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.

		Each tablet contains: Clozapine…...100mg (USP Specifications)		10.11.2023	
66.	052676	SAVERIL TABLETS 25MG Each Tablet contains: Clozapine……25mg (USP Specifications)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
67.	052677	DANREXIN TABLETS 20MG Each tablet contains: Piroxicam as Beta Cyclodextrin…20mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or uncoated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
68.	052678	Esolong Tablets 20mg Each Tablet contains: Esomeprazole as Magnesium Trihydrate..…20mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
69.	052679	Esolong Tablets 40mg. Each Tablet contains; Esomeprazole as Magnesium Trihydrate….40mg (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
70.	052680	Lanzodan Tablets 30mg Each tablet contains: Lansoprazole…...30mg (USP Specifications)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023 (Prevacid Solutab Delayed-Release Orally Disintegrating Tablets)	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
71.	052681	Pepdan Tablets 10mg. Each Tablet contains: Rabeprazole Sodium……10mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
72.	052682	Pepdan Tablets 20mg. Each Tablet contains:	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.

		Rabeprazole as Na……..20mg. (Danas's Specs)			The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
73.	052683	Sulpeol Tablets 100mg Each Tablet contains: Levosulpiride...100mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit description of dosage form (film coated or enteric coated etc.,) and reference of finished product specification with fee as per decision of 295th meeting of Registration Board
74.	052684	Monkast Tablets 4mg Each chewable Tablet contains: Montelukast……4mg. (BP Specifications)	21/10/2008 Approval of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
75.	52685	Vendep Tablets 50mg. Each tablet contains: Venlafaxine as HCl……...50mg (BP Specifications)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
76.	052686	Rabedan Capsules 20mg Each capsule contains: Rabeprazole Sodium Pellets…...20mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit the following before issuance of renewal of registration: i. Approval of source of pellets. ii. Reference of finished product specification
77.	052687	Danflu Capsule 150mg Each capsule contains: Fluconazole…...150mg (BP Specifications)	21/10/2008 Approval of change of brand name: 14.01.2015 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
78.	052688	Ribadan Capsules 400mg. Each capsule contains: Ribavirin…400mg (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
79.	052689	Xepex Capsules 20mg Each Capsule contains: Ziprasidone as HCl…..20mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board

80.	052690	Xepex Capsules 40mg. Each capsule contains: Ziprasidone as HCl……40mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board
81.	052691	Xepex Capsules 60mg. Each capsule contains: Ziprasidone as HCl……..60mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board
82.	052692	Xepex Capsules 80mg. Each capsule contains: Ziprasidone as HCl……..80mg.	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board
83.	052693	Isonas Capsule 10mg Each capsule contains: Isotretinoin ….10mg. (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Deferred for submission of Composition, batch formula, manufacturing method in line with the reference product approved in RRA. Last BMR of the product.
84.	052694	Isonas Capsule 20mg Each capsule contains: Isotretinoin……20mg. (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Deferred for submission of Composition, batch formula, manufacturing method in line with the reference product approved in RRA. Last BMR of the product.
85.	052695	Neurodan Capsule 300mg. Each capsule contains: Gabapentin……300mg. (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
86.	052696	Neurodan Capsules 100mg. Each capsule contains: Gabapentin …….100mg (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
87.	052697	Neurodan Capsules 400mg Each capsule contains: Gabapentin.400mg (USP Specifications)	21/10/2008 Approval of change of specifications: 15.08.2018	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028.
88.	052698	Orlidan Capsules 120mg. Each capsule contains: Orlistat……120mg. (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit the following before issuance of renewal of registration: i. Approval of source of pellets.

					ii. Reference of finished product specification
89.	052699	Mometaderm Cream. Each tube contains: Mometasone Furoate….0.1% (USP Specifications)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028
90.	052700	Mometaderm Ointment. Each tube contains: Mometasone Furoate……0.1% (USP Specifications)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028
91.	052701	Medan Cream. Each Tube contains: Permethrin…..5% (Danas's Specs)	21/10/2008	Rs.30000/- Dy.No.26837 10.11.2023	Renewal is granted w.e.f 21.10.2023 to 20.10.2028. The firm shall submit reference of finished product specification with fee as per decision of 295th meeting of Registration Board before issuance of renewal letter.
M/s Envoy Pharmaceuticals (Pvt) Ltd, 24th Km, Multan Road Maraka Lahore					
92.	046210	EMAGE 40MG CAPSULE Each Capsule contains: Esomeprazole as magnesium Trihydrate 40mg **Source of Pellets:** M/s Murli Krishna Pharma Pvt Limited, Shop No. 08 Pearl Building, Powai Vihar Complex, Powai India.	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. GMP certificate issued by regulatory authority of country of origin in respect of M/s Murli Krishna Pharma Pvt Limited Powai India. Copy of Certificate of analysis of last batch of pellets imported
93.	046211	Emage 20mg Capsule Each Capsule contains: Esomeprazole as magnesium Trihydrate 20mg **Source of Pellets:** M/s Murli Krishna Pharma Pvt Limited, Shop No. 08 Pearl Building, Powai Vihar Complex, Powai India	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
94.	046212	Accion 30mg Capsule Each Capsule contains: Lansoprazole 30mg	03.05.2007	Rs.30000/- Dy.No.584	-do-

		Source of Pellets: M/s Murli Krishna Pharma Pvt Limited, Shop No. 08 Pearl Building, Powai Vihar Complex, Powai India	Change of BN: 01.01.2008	Dated 09.01.2024	
95.	046213	Ometor 20mg Capsule Each Capsule contains: Omeprazole 20mg **Source of Pellets:** M/s Murli Krishna Pharma Pvt Limited, Shop No. 08 Pearl Building, Powai Vihar Complex, Powai India	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
96.	046214	Logix 10mg Tablet Each Tablet contains: Escitalopram as Oxalate 10mg	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of approval of finish product specifications. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.
97.	046215	Dolocalm 75mg Tablet Each Tablet contains: Diclofenac Potassium 75mg (BP Specifications)	03.05.2007 Approval of Change of BN: 05.05.2008	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.
98.	046216	Heptogen 200mg Tablet Each Tablet contains: Silymarin…….200mg	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012.

					Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of approval of finish product specifications. Evidence of approval of formulation in RRA.
99.	046217	Elever 20mg Tablet Each Tablet contains: Piroxicam as Cyclodextrin ……..20mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of USP which mentions the applied formulation specifications. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.
100.	046218	Cinclar 250mg Tablet Each Tablet contains: Clarithromycin.250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of USP which mentions the applied formulation specifications. Application with fee for approval of description of the applied product (film coated,

					uncoated etc.,) in line with formulation approved in RRA.
101.	046219	Cinclar 500mg Tablet Each Tablet contains: Clarithromycin 500mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
102.	046220	Mykuin 200mg Tablet Each Tablet contains: Ofloxacin 200mg (USP Specifications)	03.05.2007 Change of BN: 01.01.2008	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
103.	046221	Aligant 250mg Tablet Each Tablet contains: Levofloxacin 250mg	03.05.2007 Change of BN: 31.03.2010	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of approval of finish products specifications. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.
104.	046222	Aligant 500mg Tablet Each Tablet contains: Levofloxacin 500mg	03.05.2007 Change of BN: 31.03.2010	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
105.	046223	Peloxin 400mg Tablet Each Tablet contains: Pefloxacin as maselate dehydrate 400mg (BP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of BP which mentions the applied formulation specifications. Application with fee for approval of description of the applied product (film coated,

					uncoated etc.,) in line with formulation approved in RRA.
106.	046224	Cinspar 100mg Tablet Each Tablet contains: Sparfloxacin 100mg	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of approval of finish products specifications. Evidence of approval of formulation in RRA.
107.	046225	Axilent 400mg Tablet Each Tablet contains: Moxifloxacin HCl …….400mg	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of approval of finish products specifications. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.
108.	046226	Cefarid 500mg Capsule Each Capsule contains: Cephalexin HCl 500mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore.

					Copy of the monograph of USP which mentions the applied formulation specifications.
109.	046227	Enspor 250mg Capsule Each Capsule contains: Cefaclor 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
110.	046228	Enspor 500mg Capsule Each Capsule contains: Cefaclor 500mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
111.	046229	Droxil 500mg Capsule Each Capsule contains: Cefadroxil 500mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
112.	046230	Akurate 400mg Capsule Each Capsule contains: Cefixime 400mg (BP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of BP which mentions the applied formulation specifications.
113.	046231	Kombat 250mg Capsule Each Capsule contains: Cephradine 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of USP which mentions the applied formulation specifications.
114.	46232	Kombat 500mg Capsule Each Capsule contains: Cephradine 500mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 09.01.2024	-do-

115.	046233	Mylide 250mg Capsule Each Capsule contains: Azithromycin 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
116.	046234	Droxil 125mg Dry Suspension Each 5ml contains: Cefadroxil 125mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
117.	046235	Droxil 250mg Dry Suspension Each 5ml contains: Cefadroxil 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
118.	046236	Akurate Dry Suspension Each 5ml contains: Cefixime as Trihydrate 100mg (BP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of BP which mentions the applied formulation specifications.
119.	046237	Akurate DS dry Suspension Each 5ml contains: Cefixime as Trihydate 200mg (BP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
120.	046238	Cefarid Dry Suspension Each 5ml contains: Cephalexin 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of USP which mentions the applied formulation specifications.

121.	046239	Neonir Dry Susp Each 5ml contains: Cefdinir 125mg	03.05.2007 Change of BN 05.05.2008	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Approval of finish product specifications.
122.	046240	Kombat 250mg/5ml Dry Suspension Each 5ml contains: Cephradine 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of the monograph of USP which mentions the applied formulation specifications.
123.	46241	Kombat 125mg/5ml Dry Suspension Each 5ml contains: Cephradine 125mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
124.	046242	Enspor 125mg Dry Suspension Each 5ml contains: Cefaclor 125mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
125.	046243	Enspor 250mg Dry Suspension Each 5ml contains: Cefaclor 250mg (USP Specifications)	03.05.2007	Rs.30000/- Dy.No.584 Dated 09.01.2024	-do-
Remarks: A letter was issued to the firm for rectification of above shortcomings on 22nd January 2024. The firm has not replied yet.					

Decision: Registration Board directed to refer the case to concerned section to initiate the proceedings of cancellation of registration of all registered drugs based on cancellation of DML vide letter No. 1-54/2003-Lic (Vol-I) dated 23.12.2022.					
M/s Envoy Pharmaceuticals (Pvt) Ltd, 24th Km, Multan Road Maraka Lahore					
126.	047701	Ancip 250mg Tablet Each Tablet contains: Ciprofloxacin as HCl 250mg (USP Specifications)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of the monograph of USP which mentions the applied formulation specifications.
127.	047702	Ancip 500mg Tablet Each Tablet contains: Ciprofloxacin as HCl 500mg (USP Specifications)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	-do-
128.	047703	Novagesic 20mg Tablet Each Tablet contains: Piroxicam 20mg (USP Specifications)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	-do-
129.	047704	Bepride 25mg Tablet Each Tablet contains: Levosulpride 25mg	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated,

					uncoated etc.,) in line with formulation approved in RRA. Approval of finish product specifications.
130.	047705	Panpra 40mg Capsule Each Capsule contains: Pantoprazole 40mg (USP Specifications)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Approval of source of pellets. Copy of the monograph of USP which mentions the applied formulation specifications.
131.	047706	Rabiton 20mg Capsule Each Capsule contains: Rabeprazole 20mg (Envoy Specs)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Approval of source of pellets. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
132.	047707	Rabiton 10mg Capsule Each Capsule contains: Rabeprazole 10mg (Envoy Specs)	26.09.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	-do-
133.	047752	Renocit 5mg Tablet Each Tablet contains: Levocetrizine……5mg	23.10.2007	Rs.30000/- Dy.No.582	Notarized copy of evidence of submission of renewal

		(Envoy's Specs)		Dated 09.01.2024	application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
134.	047753	Ginobal 120mg Capsule Each Capsule contains: Ginkgobiloba 120mg (USP Specifications)	23.10.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of USP monograph which mentions the applied formulation specs.
135.	047754	Orlical 120mg Capsule Each Capsule contains: Orlistat…… 120mg (Envoy's Specs)	23.10.2007	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with

					copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Approval of source of pellets. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
136.	048374	Co-Art 20mg/120mg Tablet Each Tablet contains: Artemether20mg + Lumefantrine 120mg (Envoy's Specs)	31.01.2008	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
137.	048375	Myodine 2mg Tablet Each Tablet contains: Tizanidine HCl ….2mg (USP Specifications)	31.01.2008	Rs.30000/- Dy.No.582 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2022, 2017 and 2012. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore.

					Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of USP monograph which mentions the specs of applied formulation
Remarks: A letter was issued to the firm for rectification of above shortcomings on 22nd January 2024. The firm has not replied yet.					
Decision: Registration Board directed to refer the case to concerned section to initiate the proceedings of cancellation of registration of all registered drugs based on cancellation of DML vide letter No. 1-54/2003-Lic (Vol-I) dated 23.12.2022.					
M/s Envoy Pharmaceuticals (Pvt) Ltd, 24th Km, Multan Road Maraka Lahore					
138.	054420	Factiflox 320mg Tablet Each tablet contains: Gemifloxacin Mesylate 320mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
139.	054421	Aknidox 100mg Capsule Each Capsule contains: Doxycycline 100mg (USP Specifications)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals.

					Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore.
140.	054422	Rabipra 10mg Tablet Each tablet contains: Rabeprazole as Sodium …...10mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
141.	054423	Desgen 5mg Tablet Each Tablet contains: Desloratidine…..5mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
142.	054424	Epimax 50mg Tablet Each Tablet contains: Topiramate 50mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
143.	054425	Fluridol 100mg Tablet Each Tablet contains: Flurbiprofen 100mg (BP Specifications)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA).

					Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of BP monograph of which mentions specs for applied product.
144.	054426	Genprox 550mg Tablet Each Tablet contains: Naproxen Sodium…. 550mg (USP Specifications)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of USP monograph of which mentions specs for applied product.
145.	054427	Delide 250mg Tablet Each tablet contains: Azithromycin as Dihydrate 250mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee

					for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
146.	054428	Minobal 500mcg Tablet Each Tablet contains: Mecobalamin 500mcg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
147.	054429	Seridef 50mg Tablet Each Tablet contains: Sertraline as HCl 50mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
148.	054430	Rabipra 20mg Tablet Each Tablet contains: Rabeprazole as Sodium 20mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
149.	054431	Myodine 4mg Tablet Each Tablet contains: Tizanidine as HCl 4mg (USP Specifications)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of USP monograph of which mentions specs for applied product.
150.	054432	Ostalend 10mg Tablet Each tablet contains: Alendronate as Sodium 10mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated,

					uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
151.	054433	Neoart 20/120mg Tablet Each tablet contains: Artemether ….20mg Lumefantrine…..120mg (Envoy's Specs)	25.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
152.	054476	Neonir 250mg Capsule Each Capsule contains: Cefdinir 250mg (Envoy's Specs)	27.03.2009	Rs.30000/- Dy.No.583 Dated 09.01.2024	-do-
Remarks: A letter was issued to the firm for rectification of above shortcomings on 22nd January 2024. The firm has not replied yet.					
Decision: Registration Board directed to refer the case to concerned section to initiate the proceedings of cancellation of registration of all registered drugs based on cancellation of DML vide letter No. 1-54/2003-Lic (Vol-I) dated 23.12.2022.					
M/s Envoy Pharmaceuticals (Pvt) Ltd, 24th Km, Multan Road Maraka Lahore					
153.	060542	Deconazol 150mg Capsule Each Capsule contains: Fluconazole 150mg (Envoy's Specs)	10.10.2009	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP

					guidance vide 9-2/2022-PEC dated 18.12.2023
154.	067968	Envoytrin 20mg Capsule Each capsule contains: Fluoxetine as HCl 20mg (BP Specs)	09.12.2010	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2020 and 2015. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Copy of BP monograph which mentions specs for applied product.
155.	067969	Enspor 50mg Drops Each ml contains: Cefaclor as monohydrate 50mg (Envoy's Specs)	09.12.2010	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2020 and 2015. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
156.	067970	Nynim 20mg Capsule Each Capsule contains: Isotretinoin 20mg (USP Specs)	09.12.2010	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2020 and 2015. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA).

					Latest GMP inspection report/ certificate by DRAP Lahore. Copy of USP monograph, which mentions specs for applied product. Evidence of applied formulation in RRA.
157.	067971	Epimax 25mg Tablet Each Tablet contains: Topiramate 25mg (Envoy's Specs)	09.12.2010	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2019 and 2014. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
158.	069477	Hifer Tablet 100mg Each Tablet contains: Iron (III) Hydroxide Polymaltose Complex 100mg Folic Acid 0.35mg (Envoy's Specs)	14.04.2011	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2016 and 2021. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA.

					Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
159.	074291	Enagesic 450/35mg Tablet Each tablet contains: Paracetamol….450mg Orphenadrine ….35mg (Envoy's Specs)	07.02.2013	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2018 and 2023. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore. Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Reference of finished product specifcations in case the product is included in any of the reference pharmacopeia for grant of the same with applicable fee otherwise submit an application with fee for grant of Innovator's specifications/ Manufacturer specifcations as per DRAP guidance vide 9-2/2022-PEC dated 18.12.2023
160.	074377	Erata 10mg Tablet Each Tablet contains: Loratadine 10mg (USP specifications)	29.03.2013	Rs.30000/- Dy.No.581 Dated 09.01.2024	Notarized copy of evidence of submission of renewal application for year 2018 and 2023. Copy of post registration variation approvals (if any). Copy of valid DML and section approvals. Details of last batches manufactured along with copies of Certificate of analysis (CoA). Latest GMP inspection report/ certificate by DRAP Lahore.

					Application with fee for approval of description of the applied product (film coated, uncoated etc.,) in line with formulation approved in RRA. Copy of USP monograph, which mentions specs for applied product.
161.	074410	Etronit 100mg Tablet Each Tablet contains: Nitrofurantoin as Monohydrate 100mg (USP specifications)	04.04.2013	Rs.30000/- Dy.No.581 Dated 09.01.2024	-do-
162.	074411	Mylid 500mg Capsule Each Capsule contains: Azithromycin Dihydrate 500mg (USP specifications)	04.04.2013	Rs.30000/- Dy.No.581 Dated 09.01.2024	-do-
Remarks: A letter was issued to the firm for rectification of above shortcomings on 22nd January 2024. The firm has not replied yet.					
Decision: Registration Board directed to refer the case to concerned section to initiate the proceedings of cancellation of registration of all registered drugs based on cancellation of DML vide letter No. 1-54/2003-Lic (Vol-I) dated 23.12.2022.					
M/s. Regent Laboratories, Plot No.C-20 S.I.T.E, Super Highway Industrial Area, Karachi					
163.	030104	Klarofid Tablet 250mg Each tablet contains: Clarithromycin …. 250mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023 **Rs. 15000/-** **dated** **18.01.2024**	Renewal is granted w.e.f. 16.04.2023 to 17.04.2028 as film coated tablet and with USP Specifications.
164.	030105	Klarofid Tablet 500mg Each tablet contains: Clarithromycin …. 500mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023 **Rs. 15000/-** **dated** **18.01.2024**	Renewal is granted w.e.f. 16.04.2023 to 17.04.2028 as film coated tablet and with USP Specifications.
165.	030121	Rentolin Tablet 4mg Each tablet contains Salbutamol Sulphate eq. to Salbutamol …. 4mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023 **Rs. 15000/-** **dated** **18.01.2024**	Renewal is granted w.e.f. 16.04.2023 to 17.04.2028 with BP Specifications.
166.	030126	Regoclox Capsules 250mg Each capsule contains: Ampicillin Trihydrate eq. to Ampicillin Base …. 125mg Cloxacillin Sodium eq. to Cloxacillin Base ….125mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023	Deferred for confirmation of Capsule (penicillin) section from Licensing Division.

				Rs. 15000/- dated 18.01.2024	
167.	030127	Regoclox Capsules 500mg Each capsule contains: Ampicillin Trihydrate eq. to Ampicillin Base …. 250mg Cloxacillin Sodium eq. to Cloxacillin Base …. 250mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023 **Rs. 15000/- dated 18.01.2024**	Deferred for confirmation of Capsule (penicillin) section from Licensing Division.
168.	030182	Regofid-P Cold Tablet Each tablet contains: Triprolidine HCI …. 1.5mg Pseudoephedrine HCI …. 30mg Paracetamol …. 300mg	16.04.2003	Rs.15000/- Dy No.14836 R&I Dated 12.06.2023 **Rs. 15000/- dated 18.01.2024**	Deferred for confirmation of approval of formulation in RRA.

Remarks:

The case was placed on the 331st meeting of Registration Board wherein the firm was given final opportunity for rectification of shortcomings mentioned below. The firm has now submitted reply dated 18.01.2024.

Shortcomings (F. No.3-1/2023 (Renewal) dated 11.08.2023)	**Reply**
1. Differential fee is required under DRAP Notification No. F.7-11/2012 B&A/DRAP dated 07.05.2021 as renewal applications for year 2018 and 2023 were submitted after due date. 2. Copy of valid DML and section approval letter esp. for penicillin products. 3. Latest panel GMP inspection report. 4. Details of the last batches manufactured. 5. Copy of approval finished product specifcations. 6. Description of tablet dosage forms (film coated/uncoated etc.,) 7. Evidence of approval of formulation in Reference Regulatory Authorities as designated by Registration Board.	1. The firm has submitted differential fee of Rs. 15000/- dated 18.01.2024 each and is recorded above. 2. Request for confirmation of License and Sections has been referred to Licensing Division, Licensing division informed as under: "As per available record following decision of the CLB is reproduced: Decision by the Central Licensing Board in 272nd meeting. The Board considered and approved the additional sections in the name of M/s Regent Laboratories, Plot No. C-20, SITE Super Highway, Karachi as under: i Powder veterinary vitamin (G), ii Tablet (psychotropic), iii Capsule (Psychotropic), iv Tablet (Antibiotic), v Capsule (Antibiotic), vi Sachet (General), vii Cream/Ointment (Steroidal), viii Cream/Ointment (Non-Steroidal), ix Liquid External Preparation, x Capsule (G), xi Capsule (Cephalosporin) xii Dry Powder Suspension (Cephalosporin)" 3. GMP certificate dated 03.02.2020 based on inspection dated 09.11.2019 is submitted. 4. The firm has submitted the details of last batches manufactured except Regofid-P Cold Tablet as quota of Pseudoephedrine was not allocated. 5. The firm has submitted specs and description of applied dosage forms except Regofid-P Cold Tablet however the fee is required which is not submitted by the firm.

M/s. Regent Laboratories, Plot No.C-20 S.I.T.E, Super Highway Industrial Area, Karachi					
169.	021847	Regomin Elixir Each 5ml contains Promethazine HCI …. 5mg	28.05.1998	Rs.15000/- Dy No.14833 R&I Dated 12.06.2023 **Rs. 15000/-** **dated** **18.01.2024**	Deferred for confirmation of manufacturing facility for oral liquid from Licensing Division.
170.	021848	Protazol Suspension Each 5ml contains Metronidazole as Benzoate …. 200mg	28.05.1998	Rs.15000/- Dy No.14833 R&I Dated 12.06.2023 **Rs. 15000/-** **dated** **18.01.2024**	Deferred for confirmation of manufacturing facility for oral liquid from Licensing Division.

Remarks:
The case was placed on the 331st meeting of Registration Board wherein the firm was given final opportunity for rectification of shortcomings mentioned below. The firm has now submitted reply dated 18.01.2024.

Shortcomings (F. No.3-1/2023 (Renewal) dated 11.08.2023)	**Reply**
1. Differential fee is required under DRAP Notification No. F.7-11/2012 B&A/DRAP dated 07.05.2021 as renewal applications for year 2023 were submitted after due date. 2. Copy of valid DML and section approval letter. 3. Latest panel GMP inspection report. 4. Details of the last batches manufactured. 5. Copy of approval finished product specifcations. 6. Description of tablet dosage forms (film coated/uncoated etc.,) 7. Evidence of approval of formulation in Reference Regulatory Authorities as designated by Registration Board.	1. The firm has submitted differential fee of Rs. 15000/- dated 18.01.2024 each and is recorded above. 2. Request for confirmation of License and Sections has been referred to Licensing Division, the reply is awaited. 3. GMP certificate dated 03.02.2020 based on inspection dated 09.11.2019 is submitted. 4. The firm has submitted the details of last batches manufactured. 5. The firm has submitted specs however the fee is required which is not submitted by the firm.

M/s. Kohinoor Industries 160/B, Small Industries Estate Sahiwal.					
171.	080103	Clinco Cream 2% Each gram contains: Clindamycin Phosphate eq. to Clindamycin ……20mg (USP Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
172.	080104	Traxin E Gel 35gm Each gram contains:- Isotretinoin… 0.5mg (0.05%) Erythromycin … 20mg (2%) (Manufacturer Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
173.	080105	Eclo V Cream 2%	15/02/2016	Dy No.1601	Renewal is granted w.e.f 15.02.2021 to 14.02.2026

		Each gram contains: Clotrimazole…..20mg (2%) (B.P Specifications)		dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	
174.	080106	Fusi-Topical Cream 2% Each gram contains: Fusidic Acid…. 20mg (2%) (B.P Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
175.	080107	Patrik Ointment Each gram contains: Calcipotriol… 50mcg (0.005%) (Manufacturer Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
176.	080108	Hydrozone Cream 2.5% Each gram contains: Hydrocortisone Acetate eq. to Hydrocortisone… 25mg (2.5%) (B.P Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
177.	080109	Kortizone Cream 0.05% Each gram contains: Clobetasol Propionate…. 0.05mg (0.05%) (B.P Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
178.	080110	Safe Burn Cream 1% Each gram contains:- Silver Sulfadiazine……10mg (1%) (USP Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
179.	080111	Betanoor Cream 0.01% Each gram contains:- Betamethasone as Valerate	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026

		eq. to Betamethasone… 1mg (0.1%) (B.P Specifications)		& Dy No.2931 dated 15.02.2024 Rs.10000/-	
180.	080112	Flex Emul Gel 1.16% Each gram contains: Diclofenac Diethylammonium … 11.6mg (1.16%) eq. to Diclofenac Sodium……10mg (B.P Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
181.	080113	Mobegel Sachet Each sachet contains: Mebeverine HCl… 135mg Ispahula Husk…. 3.5g (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
182.	080114	ORSK Sachet Each sachet contains: Glucose Anhydrous……13.5gm Sodium Chloride… 2.6gm Potassium Chloride……1.5gm Trisodium Citrate dihydrate… 2.9gm (BP Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
183.	080115	Konelate Sachet Each sachet contains: Strontium Ranelate…. 2gm (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
184.	080116	Grafort Sachet Each sachet contains: Dioctahedral Smectite…3gm (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
185.	080117	Fomy C Sachet Each sachet contains: Fosfomycin as Trometamol… 3gm (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931	Renewal is granted w.e.f 15.02.2021 to 14.02.2026

				dated 15.02.2024 Rs.10000/-	
186.	080118	MKBs Pediatric Sachet Each sachet contains: Montelukast as Sodium… 4mg (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
187.	080119	Ease Up Sachet Each sachet contains: Polyethylene Glycol 13350 … 13.125gm Sodium Chloride… 0.3507gm Sodium Bicarbonate… 0.1785gm Potassium Chloride… 0.0466gm (Manufacturer's Specifications)	15/02/2016	Dy No.1601 dated 24.02.2021 Rs.10000/- & Dy No.2931 dated 15.02.2024 Rs.10000/-	Renewal is granted w.e.f 15.02.2021 to 14.02.2026
M/s. Usawa Pharmaceuticals 146-Special industrial Zone, (Export Processing Zone) Risalpur					
188.	085900	Awarose Injection Each 5ml contains: Iron (III) Hydroxide sucrose complex eq to elemental Iron……100mg (USP Specifications) **Manufacturer:** M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad.	21.12.2017	Rs.75000/- Dy No.37274 Dated 21-12-2022 & Rs.75000/- Dy Dated:10-02-2023	Renewal is granted w.e.f 21.12.2022 to 20.12.2027
Remarks: The case was deferred in 7th meeting of Renewal Sub-committee the for submission of fee Rs. 75000/- under SRO 1005(I)/2017 as renewal application was submitted on 21.12.2022 i.e. after due date but within 60 days. Now the firm has submitted the Rs.75000/- details are recorded above. The case was again placed y in the 11th meeting of Renewal Sub Committee wherein the Committee referred the case to the Registration Board.					
M/s. Max Pharmaceuticals Plot No.12 Street No.N-7 National Industrial Zone Rawat, Islamabad					
189.	066616	Celmax 100mg Capsule Each capsule contains: Celecoxib… 100mg (Max's Specs)	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020 Rs.10000/-	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
190.	066617	Celmex 200mg Capsule Each capsule contains: Celecoxib… 200mg (Max's Specs)	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit reference of finished product specifications as per decision of 295th meeting of

					Registration Board before issuance of renewal of registration.
191.	066618	Mecomars 500mcg Capsule Each capsule contains: Mecobalamin… 500mcg (Max's Specs)	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
192.	066619	Piret 20mg Capsule Each capsule contains:- Piroxicam as Beta-Cyclodextrin…. 20mg (Max's Specs)	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
193.	066436	Rebosive 10mg Tablet Each tablet contains: Rabeprazole (as Sodium)… 10mg (Max's Specs)	30/11/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 30.11.2020 to 29.11.2025 The firm shall submit description of tablet and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
194.	066437	Rebosive 20mg Tablet Each tablet contains:- Rabeprazole (as Sodium)… 20mg (Max's Specs)	30/11/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 30.11.2020 to 29.11.2025 The firm shall submit description of tablet and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
195.	066438	Merimax 100mg Chewable Tablet Each chewable capsule contains: Iron III Hydroxide Polymaltose complex eq. to Elemental Iron … 100mg (Max's Specs)	30/11/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 30.11.2020 to 29.11.2025 The firm shall submit description of tablet and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
196.	066439	Feromax 100mg Chewable Tablet Each chewable capsule contains: Iron III Hydroxide Polymaltose Complex eq.	30/11/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 30.11.2020 to 29.11.2025 The firm shall submit description of tablet and reference of finished product specifications as per decision

		to Elemental Iron … 100mg Folic Acid…. 0.35mg (Max's Specs)			of 295th meeting of Registration Board before issuance of renewal of registration.
197.	066440	Cezomax 5mg Tablet Each tablet contains:- Levocetirizine Dihydrochloride… 5mg (Max's Specs)	30/11/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 30.11.2020 to 29.11.2025 The firm shall submit description of tablet and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
198.	066622	Lanzomax 30mg Capsule Each capsule contains: Lansoprazole (as enteric coated pellets)… 30mg (Max's Specs) Source of Pellets: M/s. Vision pharmaceuticals, Islamabad	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
199.	066623	Dulset 30mg Capsule Each capsule contains:- Duloxetine (as HCl) (Pellets)… 30mg (Max's Specs) Source of Pellets: M/s. Vision pharmaceuticals, Islamabad	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
200.	066624	Dulset 60mg Capsule Each capsule contains: Duloxetine (as HCl) (Pellets)… 60mg (Max's Specs) Source of Pellets: M/s. Vision pharmaceuticals, Islamabad	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.

201.	066625	Pholnac SR 1000mg Capsule Each capsule contains: Diclofenac Sodium (sustained release pellets) … 100mg (Max's Specs) Source of Pellets: M/s. Vision pharmaceuticals, Islamabad	01/12/2010	Rs.20000/- 31.12.2015 & Dy No.31577 Dated 26.11.2020	Renewal is granted w.e.f. 01.12.2020 to 30.11.2025 The firm shall submit approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 and reference of finished product specifications as per decision of 295th meeting of Registration Board before issuance of renewal of registration.
Remarks The firm has informed that they have imported the Celecoxib API vide application No.E-833934434195 dated 13.02.2024 for their registered products above. The application is returned by the I&E section on 21.02.2024 for renewal confirmation year 2015. The firm has now submitted an application for regularization of renewal of the above products including the Celmax 100mg & 200mg capsule.					
M/s Mukhtar Enterprises, 151, Block-C, Faisal Town, Lahore					
202.	085257	Vancomycin 500Mg Injection (Powder for Concentrate for Solution for IV Infusion) Each vial contains Vancomycin (as hydrochloride)..500mg **Manufacturer & Product License Holder:** - M/s. Xellia Pharmaceutical APS Dalslandsgade 11, 2300 Copenhagen s Denmark	11/05/2018	Dy No.13302 dated 29.05.2023 Rs.60000/-	Renewal is granted w.e.f. 11.05.2023 to 10.05.2028 as per import policy for finished drugs.
203.	085258	Vancomycin 1000Mg (Powder for Concentrate for Solution for IV Infusion) Each vial contains: Vancomycin (as hydrochloride)..100mg **Manufacturer & Product License Holder:** - M/s. Xellia Pharmaceutical APS Dalslandsgade 11, 2300 Copenhagen s Denmark	11/05/2018	Dy No.13302 dated 29.05.2023 Rs.60000/-	Renewal is granted w.e.f. 11.05.2023 to 10.05.2028 as per import policy for finished drugs.
M/s. The Searle Company Limited,F-319 SITE Karachi.					
204.	86979	Dextop 60mg Capsule Each capsule contains Dexlansoprazole Dual Delayed Release Pellets eq. to Dexlansoprazole….60mg (As per *Innovator's Specifications) **Source of pellets:** Alphamed Formulations Pvt Ltd. Survay No.225, Sampanbole Village, Shamirpet (M) Ranga	28/02/2018	Dy No.28937 dated 14.12.2023 Rs.30000/- & Rs.300,000/- Dated 11.12.2023 vide Deposit slip No.213823472	Renewal is granted w.e.f. 28.02.2023 to 27.02.2028

		Reddy District, 500078, Telangana State, India			
205.	86978	Dextop 30mg Capsule Each capsule contains Dexlansoprazole Dual Delayed Release Pellets eq. to Dexlansoprazole..30mg (As per *Innovator's Specifications) **Source of pellets:** Alphamed Formulations Pvt Ltd. Survay No.225, Sampanbole Village, Shamirpet (M) Ranga Reddy District, 500078, Telangana State, India	28/02/2018	Dy No.28937 dated 14.12.2023 Rs.30000/- & Rs.300,000/- Dated 11.12.2023 vide deposit slip No.88617236155	Renewal is granted w.e.f. 28.02.2023 to 27.02.2028
M/s Revive Healthcare, 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore.					
206.	082061	Pemex Injection 500mg Each vial contains: Pemetrexed (as Pemetrexed Disodium) ….500mg (Manufacturer's Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.	08.11.2016	Rs 60000/- dated 07.01.2022 Rs. 30000/- dated 25.04.2024	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs. The firm shall also submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
207.	082062	Temotec 100mg Capsules Each capsule contains: Temozolamide USP…100mg (Manufacturer's Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.	08.11.2016	Rs 60000/- dated 07.01.2022 Rs. 30000/- dated 25.04.2024	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs. The firm shall also submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
208.	082064	Unicristin 1mg Injection Each ml contains: Vincristine Sulphate USP….1mg (USP Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.	08.11.2016	Rs 60000/- dated 07.01.2022 Rs. 30000/- dated 25.04.2024	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs.
209.	082066	Octreotide 50mcg Injection Each ampoule contains: Octreotide acetate eq. to 0.05mg of Octreotide…..50mcg	08.11.2016	Rs 60000/- dated 07.01.2022	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs.

		(Manufacturer's Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.		Rs. 30000/- dated 25.04.2024	The firm shall also submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
210.	082067	Vinotec 50mg Injection Each vial of 5ml contains: Vinorelbine as tartrate eq. to Vinorelbine…50mg (USP Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.	08.11.2016	Rs 60000/- dated 07.01.2022 Rs. 30000/- dated 25.04.2024	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs.
211.	082068	Ifomid-M 1gm Injection Each vial contains: Ifosfamide…..1gm (BP Specifications) **Manufacturer:** M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District Solan (H.P) 174101, India.	08.11.2016	Rs 60000/- dated 07.01.2022 Rs. 30000/- dated 25.04.2024	Renewal is granted w.e.f 08.11.2021 to 07.11.2026 as per import policy for finished drugs.
Remarks: CoPP issued by States Drug Controller Baddi Solan, Govt. of Himachal Pradesh India dated 09.12.2022 valid upto 22.08.2024					
M/s Davis Pharmaceutical Laboratories 121 Industrial Triangle Kahuta Road Islamabad.					
212.	024356	Asalkar Syrup Each 5ml contains: Salbutamol….2mg	27.03.2002	**4000/- dated 27.03.2012** **10000/- dated 27.01.2020 (diff of 2012)** 10000/- dated 22.03.2017 15000/- dated 25.03.2022	Renewal is granted w.e.f. 27.03.2022 to 26.03.2027 The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
Firm has submitted application for regularization of renewal of 2012 vide letter Dy. No. 5259 dated 2305.2024 w.r.t DRAP letter F.3-1/2023-PR-II dated 24.011.2023.					
M/s Bloom Pharmaceuticals Pvt Limited, Hattar					
213.	022365	Doxylide Capsule Each capsule contains: Doxycycline……100 mg	15.09.1998	Dy No.5302 dated 24.05.2024 Rs.10000/- dated 18.09.2013 & Rs.10000/- Dated 30.08.2019	Renewal is granted w.e.f. 15.09.2023 to 14.09.2028. The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.

				Rs.100000/- dated 22.10.2019 Rs.60000/- Dated 23.05.2023 Rs. 15000/- Dated: 11.09.2023	
Remarks Approval of additional pack vide letter No.F.6-38/95-Reg-II (Pt-II) dated 09.01.1999 and renewal of registration granted vide letter No.F.12-3/2006-RRR dated 20.07.2009 valid till 15.09.2013.					

Case No: 2 Renewal application submitted by M/s Merixil Pharma Office No. 28, Second floor Rose Plaza, I-8, Markaz Islamabad.

Sr. No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
214.	081801	CAPECITABINE NORMON 500MG TABLET Each film coated tablet contains: Capecitabine….500mg (USP Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain	15.09.2016 Approval of change of Brand Name: 16.04.2021	Rs.30000/- Dy.No.21303 04.08.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.
215.	081802	ONDANSETRON NORMON 8MG INJECTION (Solution for Injection) Each 4ml ampoule contains: Ondansetron (as hydrochloride dihydrate) …...8 mg (Manufacturer's Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain	15.09.2016 Approval of change of vial to ampoule: 17.04.2018	Rs.30000/- Dy.No.21304 04.08.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.
216.	081803	TEMOEIRGEN 100MG CAPSULES Each capsule contains: Temozolamide……100 mg (Manufacturer's Specification) **License Holder:**	15/09/2016	Rs.30000/- Dy.No.19358 09.01.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.

		M/s Fair-Med Healthcare GmbH Dorotheenstraβe 48 Hamburg, Germany. **Manufacturer:** M/s Eirgen Pharma Ltd., Westside Business Park Old Kilmeaden Road, Waterford Ireland			
217.	081804	TEMOEIRGEN 20MG CAPSULES Each capsule contains Temozolamide…..20 mg (Manufacturer's Specification) **License Holder:** M/s Fair-Med Healthcare GmbH Dorotheenstraβe 48 Hamburg, Germany. **Manufacturer:** M/s Eirgen Pharma Ltd., Westside Business Park Old Kilmeaden Road, Waterford Ireland	15/09/2016	Rs.30000/- Dy.No.19357 09.01.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.
218.	081805	LUTRATE 1MONTH DEPOT (3.75MG) INJECTION Each vial contains: Leuprorelin Acetate Powder for Prolonged Release Suspension for Injection…...3.75mg (Manufacturer's Specification) **Manufacturer:** M/s GP Pharma, S.A Poligono Industrial Els Vinyets-Els Fogars. Sector 2, Carretera Comarcal C244, Km, 22 08777 Sant Quinti De Mediona Barcelona, Spain.	15/09/2016	Rs.30000/- Dy.No.22079 11.08.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.
219.	081806	Sterile Solvent for Lutrate Depot Each Pre Filled Syringe 2ml contains: 0.8% Mannitol Solution in Water For Injection (Manufacturer's Specification) **Manufacturer:** M/s GP Pharma, S.A Poligono Industrial Els Vinyets-Els Fogars. Sector 2, Carretera Comarcal C244, Km, 22 08777 Sant Quinti De Mediona Barcelona, Spain.	15/09/2016	Rs.30000/- Dy.No.22080 11.08.2021	Renewal is granted w.e.f. 15.09.2021 to 14.09.2026 as per import policy for finished drugs.

220.	082058	BIOPAC 30MG/5ML INJECTION (Solution for Injection) Each ml contains: Paclitaxel…...6 mg (USP Specification) **Manufacturer:** M/s Biolyse Pharma Corporation, 59 Welland Vale Road, ST Catharines Ontario L2S 3Y2, Canada.	08/11/2016	Rs.30000/- Dy.No.29830 29.10.2021	Renewal is granted w.e.f. 08.11.2021 to 07.11.2026 as per import policy for finished drugs.
221.	082059	ZOLEDRONIC ACID NORMON 4MG/5ML INJECTABLE (Concentrate for Solution for Infusion) Each 5ml vial contains: Zoledronic Acid Monohydrate 4.264mg eq. to Zoledronic Acid 4mg (Manufacturer's Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain	08/11/2016	Rs.30000/- Dy.No.21305 04.08.2021	Renewal is granted w.e.f. 08.11.2021 to 07.11.2026 as per import policy for finished drugs.
222.	081778	Temoeirgen 250mg Capsule Each capsule contains: Temozolamide…...250 mg (As per *Innovator's Specification) **License Holder:** M/s Fair-Med Healthcare GmbH Dorotheenstraβe 48 Hamburg, Germany. **Manufacturer:** M/s Eirgen Pharma Ltd., Westside Business Park Old Kilmeaden Road, Waterford Ireland	31/03/2017	Rs.30000/- Dy.No.19358 09.07.2021	Renewal is granted w.e.f. 31.03.2022 to 30.03.2027 as per import policy for finished drugs.
223.	084588	EXEMESTANE NORMON 25MG TABLET Each film coated tablet contains: Exemestane….25 mg (As per *Innovator's Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain	05/06/2017	Rs.30000/- Dy.No.11357 11.05.2022	Renewal is granted w.e.f. 05.06.2022 to 04.06.2027 as per import policy for finished drugs.
224.	087621	IMATINIB NORMON 100MG TABLET	12.01.2018	Rs. 30000/- dated 11.11.2022	Renewal is granted w.e.f. 12.01.2023 to 11.01.2028 as per

		Each film coated tablet contains: Imatinib Mesylate 119.5mg eq. to Imatinib….100mg (As per *Innovator's Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain		Dy. No. 33084	import policy for finished drugs.
225.	087622	IMATINIB NORMON 400MG TABLET Each film coated tablet contains: Imatinib Mesylate 478 eq. to Imatinib….400mg (As per *Innovator's Specification) **Manufacturer:** M/s Laboratorios Normon, S.A. Ronda De Valdecarrizo, 6, 28760 Tres Cantos (Madrid) Spain	12.01.2018	Rs. 30000/- dated 11.11.2022 Dy. No. 33084	Renewal is granted w.e.f. 12.01.2023 to 11.01.2028 as per import policy for finished drugs.
226.	086482	LUTRATE 3 MONTH DEPOT (22.5MG) POWDER FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION Each vial contains: Leuprorelin Acetate….22.5 mg (As per *Innovator's Specification) **Manufacturer:** M/s GP Pharma, S.A Poligono Industrial Els Vinyets-Els Fogars. Sector 2, Carretera Comarcal C244, Km, 22 08777 Sant Quinti De Mediona Barcelona, Spain. Packing: 1Kit Each commercial kit contains:	15.12.2017	Rs.30000/- Dy.No.35588 07.12.2022	Renewal is granted w.e.f. 15.12.2022 to 14.12.2027 as per import policy for finished drugs.

Shortcomings (F. No. 3-1/2023-RRR dated 12.01.2024)	**Reply**
i. Legalized GMP certificate issued by regulatory authority of country of origin for M/s Eirgen Pharma Ltd., Westside Business Park Old Kilmeaden Road, Waterford Ireland as the CoPP submitted do not indicate the GMP status of the manufacturer. ii. As per CoPP submitted in respect of Zoledronic Acid Normon 4mg/5ml Injectable (082059), the	i. The firm has submitted the legalized CoPP issued by BfArM Germany along with the requisite fee. ii. The firm has submitted Eudra GMP certificate of the manufacturer i.e. M/s Eirgen Pharma Ltd., Westside Business Park Old Kilmeaden Road, Waterford Ireland for Temoeirgen 25, 100 and 250mg capsules.

product is not available in the market in Spain. Justification/ clarification from the manufacturer or preferably from regulatory authority is required. iii. Notarized sole agency agreement/ letter of authorization for all applied products from the product license holder abroad. iv. Copy of invoice of last batch imported along with the certificate of analysis (CoA) and DRAP clearance certificate. v. Copy of approval of change of address of Product License Holder as the name mentioned on the submitted CoPP varies from the address on registration letter for Temoeirgen 20mg, 100mg & 250mg Capsules. vi. Copy of valid drug sale license	iii. The firm has submitted the notarized sole agency agreement/ letter of authorization for all applied products from the product license holder abroad. iv. The firm has submitted copies of invoice and clearance certificates. v. The firm has submitted the legalized CoPP wherein the address of the PLH is updated only. The firm has submitted the requisite fee. vi. Valid DSL has been submitted having same address and name as of registration letters.

Case No. 3 G-Sol NS 500ml Infusion of M/s Gallop Water Sciences Lahore

M/s Gallop Water Sciences Lahore has requested to register their following previously registered product as the renewal of registration of was delayed by more than one year due to their negligence. Details are as under:

Sr.No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Renewal application (R&I) Fee submitted
227.	081824	GEE-SOL NS 500 ML Contains: Sodium chloride… 4.5 gm (0.9% w/v)	18-10-2016	30000/- dated 17.05.2023

The firm informed that they had applied for the registration of above product on 18.04.2023 on Form 5F as per requirements. They have requested to grant registration with the above mentioned brand name and registration number.

Decision: Registration Board directed to refer the matter to PEC to process the new registration application submitted by the firm on Form-5F dated 18.04.2023 for above product as per decision of the Authority.

Case No. 4 M/s. Hassan Brothers House P-318 Street No.06 Ffatah Abad Sharki, Faisalabad

It is submitted that below mentioned product registered in name of M/s. **Hassan Brothers House P-318 Street No.06 Ffatah Abad Sharki, Faisalabad**. Wherein the board decided as under:

Sr.No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Renewal application (R&I) Fee submitted	Decision
228.	082807	Peperoxin Solution Each liter Contains. Pefloxacin……100 mg (as Pefloxacine Methanesulfonate…….. 139.6g) (As per Innovator's Specifications) **Manufacturer:** M/s. Samyang Anipharm Co., Ltd 35	08.06.2018	Rs.30000/- Dated 17.05.2023	Renewal is granted w.e.f 08.06.2023 to 07.06.2028 as per import policy for finished drugs.

		Songseon-ro 265 beon-gil Pocheonsi, Gyconggi-do, Korea			
Remarks: Legalized certificate of free sales issued by Animal and plant Quarantine Agency, Republic of Korea dated 04.07.2023 Legalized GMP certificate dated issued by Animal and plant Quarantine Agency, Republic of Korea dated 16.02.2023					

Case No: 5 Renewal application submitted after due date but within prescribed time period under Ru

le 27 of Drug (LR&A) Rules 1976 by M/s Liven Pharmaceuticals (Pvt) Ltd.49-km, Multan Road, Lahore

Sr.No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
229.	091546	Oma 40mg capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……40mg (USP Specification) **Source of Pellets:** M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
230.	091545	Oma 20mg capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole…20mg (USP Specification) **Source of Pellets:** M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
231.	091544	Livocetamol 1g/100ml infusion Each ml contains Paracetamol…...10mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
232.	091543	Livgyl 500mg/100ml Infusion Each ml contains: Metronidazole….5mg (BP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
233.	091542	Defung 100mg/50ml Infusion Each ml contains: Fluconazole….2mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

234.	091541	Ofon 200mg/100ml Infusion Each ml contains: Ofloxacin…2mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
235.	091540	Levon 500mg/100ml infusion Each ml contains: Levofloxacin (as hemihydrate) ….5mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
236.	091539	Renoval 400mg/250ml infusion Each ml contains: Moxifloxacin (as hydrochloride) ….1.6mg (As per innovator's Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
237.	091538	Diclosed 75mg/3ml Injection Each ml contains: Diclofenac sodium….25mg (As per Innovator's Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
238.	091537	L-D3 5mg/ml Injection Each ml contains: Cholecalciferol…5mg (BP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
239.	091536	Nalax 0.4mg/ml Injection Each ml contains: Naloxone as HCl…0.4mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
240.	091535	Ondaset 2mg/ml Injection Each ml contains: Ondansetron…2mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
241.	091534	Ketoliv 30mg/ml Injection Each ml contains: Ketorolac Tromethamine…30mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
242.	091533	Ketolive 10mg/ml Injection Each ml contains: Ketorolac Tromethamine….10mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
243.	091532	N-Bin 10mg/ml Injection Each ml contains: Nalbuphine HCl….10mg	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

		(As per innovators Specification)			
244.	091531	N-Bin 20mg/ml Injection Each ml contains: Nalbuphine HCl…20mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
245.	091530	Ondaset 4mg/2ml Injection IM/IV Each ml contains Ondansetron as hydrochloride…2mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
246.	091529	Livobal 500mcg/ml Injection Each ml contains: Mecobalamin..500mcg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
247.	091527	Daizelive 10mg/2ml Injection Each ml contains: Diazepam…5mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
248.	091526	Topas Sachet 135mg/3.5gm Each sachet contains; Mebeverine…….135 mg Psyllium Husk….3.5 g	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
249.	091525	Stran Sachet 2gm Each sachet contains: Strontium ranelate…2gm (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
250.	091524	Livair Sachet 4mg Each sachet contains: Montelukast sodium granules eq. to Montelukast….4mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
251.	091523	Lenvir 1mg Tablets Each film coated tablet contains: Entecavir (as monohydrate)…1mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
252.	091522	Lenvir 0.5mg Tablets Each film coated tablet contains: Entecavir (as monohydrate) …0.5mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
253.	091521	Napolive 500mg Tablets Each film coated tablet contains: Naproxen……500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
254.	091520	Napolive 250mg Tablets	24.07.2018	Dy No.19276	

		Each film coated tablet contains: Naproxen…….250mg (USP Specification)		Rs.15000/- dated 02.08.2023	
255.	091519	Ciprotab 500mg tablet Each film coated tablet contains: Ciprofloxacin (as HCl)…….500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
256.	091518	Ciprotap 250mg Tablet Each film coated tablet contains: Ciprofloxacin (as HCl) ….250mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
257.	091517	Aril 10mg Tablets Each film coated tablet contains: Cetirizine 2HCl eq. to Cetirizine….10mg (BP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
258.	091516	Livazole 2.5mg Tablets Each film coated tablet contains: Letrozole…2.5mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
259.	091515	Atavast 40mg Tablets: Each film coated tablet contains: Atorvastatin (as calcium trihydrate)….40mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
260.	091514	Atavast 20mg Tablets Each film coated tablet contains: Atorvastatin (as calcium trihydrate) … 20mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
261.	091513	Atavast 10mg Tablets Each film coated tablet contains: Atorvastatin (as calcium trihydrate)10mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
262.	091512	Rvastine 20mg Tablets Each film coated tablet contains: Rosuvastatin (as Rosuvastatin calcium) … 20mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
263.	091511	Rvastine 10mg Tablets Each film coated tablet contains:	24.07.2018	Dy No.19276	

		Rosuvastatin (as Rosuvastatin calcium) ….10mg (As per Innovators Specification)		Rs.15000/- dated 02.08.2023	
264.	091510	Rvastine 5mg Tablets Each film coated tablet contains Rosuvastatin (as Rosuvastatin calcium)……5mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
265.	091509	Renoval 400mg Tablets Each film coated tablet contains: Moxifloxacin (as hydrochloride) …400mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
266.	091508	Levon 500mg Tablet Each film coated tablet contains: Levofloxacin (as hemihydrate) …500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
267.	091507	Levon 250mg Tablet Each film coated tablet contains: Levofloxacin (as hemihydrate) …250mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
268.	091506	Livadine 60mg capsule Each capsule contains: Fexofenadine…60mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
269.	091505	Livoxetine 20mg capsule Each capsule contains: Fluoxetine hydrochloride….20mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
270.	091504	Grepalin 50mg capsule Each capsule contains: Pregabalin….50mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
271.	091503	Grepalin 100mg capsule Each capsule contains: Pregabalin….100mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
272.	091502	Grepalin 75mg capsule Each capsule contains: Pregabalin…..75mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
273.	091501	Pentilive 300mg capsule Each capsule contains: Gabapentin...300 mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

274.	091500	Defung 150mg capsule Each capsule contains: Fluconazole…150mg (JP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

Shortcomings **(F. No.3-1/2023 (Renewal) dated 15.08.2023)**	**Reply** **Dy No.21650 dated 01.09.2023**
i. Differential fee of Rs. 15000/- each is required under DRAP Notification No. F.7-11/2012 B&A/DRAP dated 07.05.2021 as renewal applications for year 2023 was submitted after due date. ii. Evidence of purchase, IQ, OQ & PQ of Liquid Particle Counter and TOC Analyser as per condition of registration. Testing details need to be submitted as evidence. iii. Copy of valid DML. iv. Copy of section approval letters issued by Licensing Disvion. v. Brief details of last batches manufactured. vi. Copies of post registration variation approvals (if any). vii. Undertaking that applied products granted "As per Innovators specifcations" are not yet included in any of the reference pharmacopeia, however in case of inclusion submit evidence of submission of application for grant of pharmacopeial specs or copy of approval if any. viii. Latest GMP inspection report.	i. The firm has submitted the copy of request letter to CEO DRAP dated 02.08.2023 for justification of 3days delay due in accessibility to www.fee.dra.gov.pk and in ability to generate fee challans for submission, and it was neither in our power nor approach to use any alternate method. The detail of the letter is as under: *"There were holidays for Ashura and then Islamabad local holidays due to a visit of his Excellency Deputy Prime minister of People's Republic of china and we are submitting on the first working day after the debatable date of registration letter. The date of registration letter is 24th of July 2018 but letter signed and received by us was on dated 12th August, 2018".* ii. The firm has submitted the copy of delivery challan dated 10.10.2018 LPC and 14.11.2018 for TOC Analyzer. However, the IQ, OQ and PQ report was generated on 24.01.2023 which was completed on 15.08.2023. Testing details have not been submitted. iii. Firm has submitted copy of application submitted for renewal of DML dated 12.12.2022. iv. The firm has submitted copy of section approval letter. v. The firm has submitted copies of approval of change of specs and copies of request submitted for grant of pharmacopeial specs. vi. The firm has submitted copy of request dated 19.07.2022 to DRAP Lahore for GMP inspection/ certificate.

Proceedings:

The Board was apprised as per date of registration the renewal due date was 23.07.2023. and on the due date was Sunday which is an official holiday hence the firm can submit the fee on 24th July 2023. However it was submitted on 02.08.2023 with single fee in DRAP R&I. Moreover, the Ashura holidays were notified by the Government 28-29th July 2023 (Friday & Saturday). Moreover, the Chinese Premier arrived in Islamabad on 31st July 2023 and remained here till 2nd July 2023 and there no local holiday announcement for Government Offices including DRAP. Hence the stance of the firm is not justified. The RRR section has checked from the B&A Division regarding the submission of fee specifically renewal submission fee/ challan generation from and it was found that challan were created and even the fee was submitted in the month of July till the due date i.e. 24.07.2023.

Decision in 331st meeting of Registration Board:

Keeping in view the position narrated above. Registration Board directed the firm to submit differential fee before next meeting. In case of non-compliance, proceedings for suspension of registration shall be initiated under Rule 27 of Drug (LR&A) Rules 1976 and under section 42 of Drug Act 1976.

Accordingly, above decision of the Board was communicated to the firm vide letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023.The reply of the firm with reference to the aforesaid letter is reproduced verbatim.

Now firm reply as under:

Reference to the letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023 reached to us on 14th December, 2023 on our address 49-Km Multan Road Lahore the firm has requested as under: I am writing to appeal against the decision mad regarding renewal of registration of drugs Act 1976 and rules framed there under, The decision, as it stands appears to be disproportionately harsh and fails to align with the principles of justice due to the absence of a fair hearing and inadequate representation of our case. Upon careful consideration of the circumstances it is evident that our side of the case was not effectively presented or advocated for during the proceedings. We believe that key aspects of our situation were not adequately communicated leading to an unfair and unjust conclusion. Moreover, I which to emphasize that we have diligently fulfilled our obligations by depositing the standard fee hence indication our compliance with the prescribed regulations. As such the intimation of section 42, pertaining to non-compliance, appears to be erroneous in our case. Our primary plea is to request a waiver of the fine imposed which we firmly believe is unjustified and disproportionate given our adherence to the prescribed standards and regulations the imposition of the this fine under the circumstances appears to be arbitrary and not in line with the intended purpose of the regulations. We respectfully request a reconsideration of the decision, emphasizing our commitment to complying with all regulations and providing any necessary documentation or evidence to support our position. Furthermore, we seek and opportunity for a fair and comprehensive hearing where our case can be properly presented allowing for adjust and informed decisions to be made. I trust that your esteemed office/ board will carefully review the details provided and grant us the opportunity to present our case in a fair and unbiased setting your understanding and reconsideration in this matter will be highly appreciated.

Decision: **Keeping in view the response of the firm as recorded above with reference to DRAP letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023, Registration Board decided to give opportunity of personal hearing to the firm under section 42 of the Drug Act 1976.**

Case No: 6 **Submission of new/fresh registration applications after cancellation of registration due to non-submission/ submission of renewal after the prescribed time period as per decision of DRAP Authority in its 180thmeeting**

The DRAP Authority in its180th meeting held on 07th March 2024 while considering the application of M/s Gray's Pharmaceuticals Rawat decided as under:

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i. Shall be considered out-of-queue and

ii. Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.

2. No such cases shall be forwarded to the Authority and shall be decided on the same analogy by the Division of PE&R and BE&R.

Keeping in view the above decision of the following new registration applications have been submitted on Form-5:

1. M/s Z-Jan Pharmaceutical Industries (Pvt) Limited, Peshawar

1.	Brand Name + Dosage Form and Strength	Zoclan Injection (IV)
	Composition	Each vial contains: Ceftriaxone 250mg
	Dairy No. date of R &I fee	5128 dated 20.05.2024 Rs.30000/-

	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s Vial
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Zeporin Injection 1gm (059454) cancelled vide DRAP letter No. 3-5/2021-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
2.	Brand Name + Dosage Form and Strength	Emexin Injection 500mg
	Composition	Each vial contains: Cefotaxime(as sodium) 500mg
	Dairy No. date of R &I fee	5108 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s Vial
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Emexin Injection 500mg (059462) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
3.	Brand Name + Dosage Form and Strength	Linzee Injection
	Composition	Each ml ampoule contains:- Lincomycin (as HCl) 300mg
	Dairy No. date of R &I fee	5127 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification
	Pack size and Demand Price	5x1ml ampoule, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Linzee Injection (059482) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
4.	Brand Name + Dosage Form and Strength	Zelium Suspension
	Composition	Each 5ml contains: Domperidone (Ph. Eur)…5mg
	Dairy No. date of R &I fee	5106 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specification
	Pack size and Demand Price	60ml, 120ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.

	Remark of the Renewal section	Registration of Zelium Suspension (045948) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved as per Innovator's Specifcations. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
5.	Brand Name + Dosage Form and Strength	Lamin Injection
	Composition	Each 1ml ampoule contains:- Mecobalamin (JP) 500mcg
	Dairy No. date of R &I fee	5101dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer
	Pack size and Demand Price	10x1ml ampoule, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Lamin Injection (059478) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved as per Innovator's Specifcations. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
6.	Brand Name + Dosage Form and Strength	Emexin Injection 1gm
	Composition	Each vial contains:- Cefotaxime(as sodium)..... 1gm
	Dairy No. date of R &I fee	5118 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Emexin Injection 1gm (059463) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
7.	Brand Name + Dosage Form and Strength	Cefep 1gm Injection
	Composition	Each vial contains:- Cefepime (as HCl) with sterile arginine USP..... 1gm
	Dairy No. date of R &I fee	5107 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Cefep 1gm Injection (059467) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	

8.	Brand Name + Dosage Form and Strength	Nilvom Injection 50mg
	Composition	Each ml ampoule contains:- Dimenhydrinate USP 50mg
	Dairy No. date of R &I fee	5120 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1ml ampoule Pack of 25's, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Nilvom Injection 50mg (059480) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
9.	Brand Name + Dosage Form and Strength	Cefep Injection
	Composition	Each vial contains:- Cefepime (as HCl) with sterile arginine 500mg
	Dairy No. date of R &I fee	5115 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Cefep Injection (059466) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
10.	Brand Name + Dosage Form and Strength	Oxa-Z infusion
	Composition	Each ml of solution for infusion contains:- Levofloxacin as hemihydrate 5mg
	Dairy No. date of R &I fee	5102 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	JP Specifications
	Pack size and Demand Price	100ml in glass vial, as per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Oxa-Z infusion (059451) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
11.	Brand Name + Dosage Form and Strength	Zoclan Injection 500mg (IV)
	Composition	Each vial contains:- Ceftriaxone (as sodium)..... 500mg
	Dairy No. date of R &I fee	5126 dated 20.05.2024 Rs.30000/-

	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1s Vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Zoclan Injection 500mg (059455) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
12.	Brand Name + Dosage Form and Strength	Azosul Injection 1gm
	Composition	Each vial contains:- Cefoperazone (as sodium)....500mg, Sulbactam (as sodium) 500mg
	Dairy No. date of R &I fee	5126 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	JP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar
	Remark of the Renewal section	Registration of Azosul Injection 1gm (059456) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
13.	Brand Name + Dosage Form and Strength	Azosul Injection 500mg
	Composition	Each vial contains:- Cefoperazone (as sodium)....250mg, Sulbactam (as sodium) 250mg
	Dairy No. date of R &I fee	5104 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	JP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Azosul Injection 500mg (059457) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
14.	Brand Name + Dosage Form and Strength	Xocrel Capsule 40mg
	Composition	Each capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to: Esomeprazole (USP)…40mg
	Dairy No. date of R &I fee	5111 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5

	Finished product specifications	USP specifications
	Pack size and Demand Price	14s, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Xocrel Capsule 40mg (059486) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Source of pellets is not mentioned in Form-5.	
	Decision: Approved. Registration letter shall be issued after submission of source of pellets and valid GMP certificate/ GMP inspection report.	
15.	Brand Name + Dosage Form and Strength	Xocrel Capsule 20mg
	Composition	Each capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to: Esomeprazole (USP)…20mg
	Dairy No. date of R &I fee	5109 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	14s, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Xocrel Capsule 20mg (059487) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Source of pellets is not mentioned in form-5.	
	Decision: Approved. Registration letter shall be issued after submission of source of pellets and valid GMP certificate/ GMP inspection report.	
16.	Brand Name + Dosage Form and Strength	Oxirase Infusion
	Composition	Each ml of solution for infusion contain: Ciprofloxacin USP..... 2mg (As ciprofloxacin lactate)
	Dairy No. date of R &I fee	5125 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	100ml glass vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Oxirase Infusion (059449) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
17.	Brand Name + Dosage Form and Strength	Azour 200mg/5ml powder for oral Suspension
	Composition	Each 5ml contains: - Azithromycin (as dihydrate) USP 200mg
	Dairy No. date of R &I fee	5124 dated 20.05.2024 Rs.30000/-

	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	15ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Azour 200mg/5ml Suspension (032062) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
18.	Brand Name + Dosage Form and Strength	Depset Tablet 20mg
	Composition	Each tablet contains:- Fluoxetine (as HCl) 20mg
	Dairy No. date of R &I fee	5123 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1x10s blister pack, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Depset Tablet 20mg (059447) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
19.	Brand Name + Dosage Form and Strength	Z-JANS Water
	Composition	Each ml contains: Water for Injection 5ml
	Dairy No. date of R &I fee	5122 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	5ml ampoules, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Z-JANS Water (059475) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
20.	Brand Name + Dosage Form and Strength	Irozee Injection
	Composition	Each ml contains: Iron Sucrose 20mg
	Dairy No. date of R &I fee	5121 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	5x5ml ampoules, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.

	Remark of the Renewal section	Registration of Irozee Injection (059483) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
21.	Brand Name + Dosage Form and Strength	Irozee Syrup
	Composition	Each 5ml contains: Elemental Iron as Iron Hydroxide Polymaltose Complex……50mg
	Dairy No. date of R &I fee	5119 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	120ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Irozee Syrup (045945) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved as per Innovator's specifications. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
22.	Brand Name + Dosage Form and Strength	Emexin Injection 250mg
	Composition	Each vial contains:- Cefotaxime (Na) 250mg
	Dairy No. date of R &I fee	5117 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1s vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Emexin Injection 250mg (059461) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
23.	Brand Name + Dosage Form and Strength	Revicel Syrup
	Composition	Each 5ml contains:- Iron (as Polysaccharide Complex)……100mg
	Dairy No. date of R &I fee	5116 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	120ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Revicel Syrup (045946) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.

	Decision: Approved as per Innovator's specifications. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
24.	Brand Name + Dosage Form and Strength	Kufzee Syrup
	Composition	Each 5ml contains: Diphenhydramine HCl……5mg Dextromethorphan HBr……6.25mg
	Dairy No. date of R &I fee	5114 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	120ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Kufzee Syrup (045947) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Deferred for submission of evidence of approval of formulation in RRA or Formulation approved by the DRAP	
25.	Brand Name + Dosage Form and Strength	Oxirase Infusion
	Composition	Each ml of solution for infusion contain: Ciprofloxacin USP..... 4mg (As ciprofloxacin lactate)
	Dairy No. date of R &I fee	5112 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	100ml vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Oxirase Infusion (Ciprofloxacin 2mg/ml, 100ml vial) (059449) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: The above product is applied against cancellation of registration of Oxirase Infusion (Ciprofloxacin 2mg/ml).	
26.	**Decision: Registration Board rejected the application of Oxirase Infusion (Ciprofloxacin 4mg/ml, 100ml vial) as the registration of the product cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 bears strength of Ciprofloxacin 2mg/ml, 100ml vial. The application of the Ciprofloxacin 2mg/ml, 100ml vial is already considered at Sr. No. 16 of Case No. 6(1) above.**	
27.	Brand Name + Dosage Form and Strength	Examic Injection 250mg
	Composition	Each amp contains: Tranexamic Acid 250mg
	Dairy No. date of R &I fee	5113 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	5nlx10s ampoule, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Examic Injection 250mg (059484) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312)

		dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
28.	Brand Name + Dosage Form and Strength	Parasol Suspension
	Composition	Each 5ml contains: - Paracetamol BP …250mg.
	Dairy No. date of R &I fee	5110 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	60ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Parasol Plus Suspension (045944) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
29.	Brand Name + Dosage Form and Strength	Examic Injection 500mg
	Composition	Each 5ml ampoule contains: Tranexamic Acid B.P 500mg
	Dairy No. date of R &I fee	5105 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10x5ml ampoule, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Examic Injection 500mg (059485) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
30.	Brand Name + Dosage Form and Strength	Rinai Injection
	Composition	Each 2ml ampule contains Ranitidine as HCl 50mg
	Dairy No. date of R &I fee	5103 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10x2ml ampoule, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Rinai Injection (059481) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Deferred as per decision of Registration Board in its 294th meeting for ranitidine containing products du to risk of NDMA impurities.	
31.	Brand Name + Dosage Form and Strength	Cesef 100mg Powder for oral Suspension

	Composition	Each 5ml (after reconstitution) contains:- Cefixime Trihydrate eq. to Cefixime (USP)……100mg
	Dairy No. date of R &I fee	5100 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	30ml and 60ml bottle, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Cesef Suspension 100mg/5ml (032288) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	
32.	Brand Name + Dosage Form and Strength	Slewel Tablet 7.5 mg
	Composition	Each tablet contains: Midazolam (maleate) Equivalent to midazolam B.P….7.5mg
	Dairy No. date of R &I fee	5099 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	1x10s Blister pack, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Slewel Tablet 7.5 mg (064329) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved as per Innovator's specifications. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report	
33.	Brand Name + Dosage Form and Strength	Azogyl Infusion
	Composition	Each ml solution for infusion contains: Metronidazole USP 5mg
	Dairy No. date of R &I fee	5098 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	500mg/100ml in glass vial, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Azogyl Infusion (059453) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report	
34.	Brand Name + Dosage Form and Strength	Lofsim Injection
	Composition	Each 3ml ampoule contains:- Diclofenac Sodium 75mg
	Dairy No. date of R &I fee	5097 dated 20.05.2024 Rs.30000/-
	Type of form	Fom-5

	Finished product specifications	USP Specifications
	Pack size and Demand Price	5x3ml ampoule, As per SRO
	GMP Status	GMP certificate dated 07.08.2018 valid till 02.08.2019 issued by DRAP Peshawar.
	Remark of the Renewal section	Registration of Lofsim Injection (059479) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate/ GMP inspection report.	

2. M/s Gray's Pharmaceuticals, Plot No.2 Street No. N-3, National Industrial Zone Rawat, Islamabad

1.	Brand Name + Dosage Form and Strength	Es-Itopram Tablets 10mg.
	Composition	Each film coated tablet contains: Escitalopram as oxalate 10mg
	Dairy No. date of R &I fee	5352 dated 27.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	14s, As per SRO
	GMP Status	
	Remark of the Renewal section	The above product was registered at M/s Gray's Pharmaceuticals, Plot No. 442, Street 7 I-9/2 Islamabad on 08.01.2008 vide No. 048040 and brand name was change to Es-itopram tablet on 13.08.2008. The registration was invalid due to submission of renewal application for year 2018 after prescribed time period (minutes of 313rd meeting of Registration Board).
2.	Brand Name + Dosage Form and Strength	Grayzine Tablet 10mg
	Composition	Each film coated tablet contains:- Cetirizine dihydrochloride 10mg
	Dairy No. date of R &I fee	5353 dated 27.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1x10s tablet, As per SRO
	GMP Status	
	Remark of the Renewal section	The above product was registered at M/s Gray's Pharmaceuticals, Plot No. 442, Street 7 I-9/2 Islamabad on 08.09.2004 vide No. 033328. The registration was invalid due to non-submission of renewal application for year 2019 (minutes of 313rd meeting of Registration Board).
3.	Brand Name + Dosage Form and Strength	Axodine tablet 180mg
	Composition	Each film coated tablet contains: Fexofenadine HCl 180mg
	Dairy No. date of R &I fee	5351 dated 27.05.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1x10s, Blister pack, As per SRO,

	GMP Status	
	Remark of the Renewal section	The above product was registered at M/s Gray's Pharmaceuticals, Plot No. 442, Street 7 I-9/2 Islamabad on 26.07.2004 vide No. 033330. The registration was invalid due to non-submission of renewal application for year 2019 (minutes of 313rd meeting of Registration Board).

As per facts mentioned in minutes of 313rd and 316th 327th meeting of Registration Board, it is submitted that the firm on 10.10.2011 requested for transfer of registration of their registered products products from existing facility i.e. M/s Grays Pharmaceuticals Plot No. 442 Street No. 7 Sect I-9/s2 Industrial Area Islamabad to their new licensed manufacturing facility i.e. M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat, which was granted DML vide approval No. 1-7/2008-Lic dated 22.06.2008. Accordingly, the request of the firm was considered in 233rd meeting of Registration Board held on 15.06.2012 wherein the Board decided to accede the request of for transfer of registrations to M/s Grays Pharmaceuticals Rawat from M/s Grays Pharmaceuticals Islamabad subject to fulfillment of latest fee requirements and confirmation of sections. As per decision of the Board the firm submitted the requisite fee. However, the letter of transfer of registration to new facility couldn't be issued. The registration letters of other products based on approval of 233rd meeting of Registration Board had been issued after approval by the Board in above mentioned meetings but these above products were deferred for confirmation of renewal submission and PRV approvals if any. Now the firm has submitted above applications in light the decision of the Authority in its 180th meeting.

Decision: **Keeping in view the position explained above, Registration Board approved the grant of registration of Es-Itopram Tablets 10mg (Escitalopram as oxalate), Grayzine Tablet 10mg (cetirizine dihydrochloride) and Axodine tablet 180mg (Fexofenadine HCl) in name of M/s Gray's Pharmaceuticals, Plot No.2 Street No. N-3, National Industrial Zone Rawat, Islamabad**

Case No: 7 Extension in contract manufacturing applied by Haleon Pakistan Limited Karachi (formerly M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited)

Sr. No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision
275.	108631	Panadol Forte Suspension Each 5ml contains: Paracetamol…250mg (BP Specifications) **Manufacturer:** M/s GlaxoSmithKline Pakistan Limited, F-268 SITE Karachi.	**11.06.2021** Approval of change of registration status: 10.07.2023	Rs. 75000/- dated 27.11.2023	

The above permission was valid for a period of thirty months under Rule 21 (a)(c) of Drug (LR&A) Rules 1976. The firm has requested extension till December 2024 to avoid shortage in market.

Decision: Registration Board considered the request of firm and granted extension in contract manufacturing till 31st December 2024 under Rule 20A (1)(c) of Drug (LR&A) Rules 1976.

Case No: 8 Renewal applications referred by Renewal Sub-Committee in its 12th meeting to the Registration Board which were submitted after due date but within prescribed time period under Rule 27 of Drug LR&A Rules 1976.

i. M/s Islam Pharmaceuticals, 7 km Pasrur Road Sialkot

Sr. No.	Tracking Number	Reg. No	Brand Name, Composition & Specifications	Date of Reg	Date of application Fee details	Decision

1.	4DR-HS1-HX29	094282	Trapam Capsule 50mg Each capsule contains: Tramadol HCl....50mg British Pharmacopeia	31/12/2018	27/02/2024 Slip No. 562273780782 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
2.	7QH-QLU-7L5H	094287	Mozole Sachet 20/1680mg Sodium Each sachet contains: Omeprazole....20mg Sodium bicarbonate....1680mg (As per Innovators Specification)	31/12/2018	27/02/2024 Slip No. 51994158 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
3.	A9Z-XQ8-NE6P	094289	Mineviz Sachet Each sachet contains: Glucose anhydrous....13.50gm Potassium chloride....1.50gm Trisodium Citrate....2.90gm Sodium chloride....2.60gm (As per Innovators Specifications)	31/12/2018	27/02/2024 Slip No. 6867674800 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
4.	AJW-LWD-VME5	094288	Focimol Sachet 3g Each sachet contains: Fosfomycin Trometamol eq. to Fosfomycin....3g (As per Innovators Specifications)	31/12/2018	27/02/2024 Slip No. 39276126992 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
5.	GG4-RWV-5D23	094286	Menop Sachet 2gm Each sachet contains: Strontium ranelate....2gm (As per Innovators Specification)	31/12/2018	27/02/2024 Slip No. 47185641 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
6.	HHD-QEQ-9GMU	094284	Lufther Dry Suspension 15/90mg/5ml Each 5ml reconstituted suspension contains: Artemether....15mg Lumefantrine....90mg (International Pharmacopeia Specifications)	31/12/2018	27/02/2024 Slip No. 9866585001 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
7.	HJX-NZG-Y8MD	094285	Montisim Granules/Sachet 4mg Each sachet contains: Montelukast as sodium....4mg (Granules for Oral Suspension) (USP Specifications)	31/12/2018	27/02/2024 Slip No. 4351914089 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
8.	J48-GWA-LG7A	094283	Antiz Capsule 250mg Azithromycin (as Dihydrate)....250mg (USP Specifications)	31/12/2018	27/02/2024 Slip No. 56616629878 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028

9.	MR2-LVP-VYH4	094280	Isflo Capsule 150mg Each capsule contains: Fluconazole....150mg (BP Specifications)	31/12/2018	27/02/2024 Slip No. 516443004 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028
10.	S2Z-6EM-LHEH	094281	Tamis Capsule 0.4mg Each Modified Release Capsule Contains: Tamsulosin hydrochloride sustained release pellets eq. to Tamsulosin hydrochloride.....0.4mg (USP Specifications) **Source of Pellets:** Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	31/12/2018	27/02/2024 Slip No. 54569891 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.
11.	41Z-JSN-5XMW	094277	Mozole Capsule 40mg Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole....40mg (USP Specification) **Source of Pellets:** Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	31/12/2018	26/02/2024 Slip No. 77759148609 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
12.	8E2-HJQ-6352	094275	Espharm Capsule 40mg Each capsule contains: Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole....40mg United States Pharmacopeia **Source of Pellets:** Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	31/12/2018	26/02/2024 Slip No. 72605663089 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
13.	9M2-RBB-NT6R	094279	Isflo Capsule 50mg Each capsule contains: Fluconazole....50mg (BP Specifications)	31/12/2018	26/02/2024 Slip No. 0866953188 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.

14.	DUU-EHH-4YHY	094273	Hemifol Tablet 100/0.35mg Each tablet contains: Iron (III) Hydroxide Polymaltose complex eq. to Elemental Iron....100mg Folic Acid....0.35mg (As per Innovators Specifications)	31/12/2018	26/02/2024 Slip No. 7022116628 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.
15.	LP3-NDZ-3J33	094272	Antem Tablet 10/10mg Each delayed release film coated tablet contains: Doxylamine Succinate....10mg Pyridoxine Hydrochloride....10mg As per Innovators Specification	31/12/2018	26/02/2024 Slip No. 66538850 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.
16.	Y9S-Y5G-6GU9	094271	Hipour Tablet 80mg Each film coated tablet contains: Febuxostat....80mg As per Innovators Specification	31/12/2018	26/02/2024 Slip No. 18467572673 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.
17.	YW9-HAT-9ZZM	094278	Tranic Capsule 250mg Each capsule contains: Tranexamic acid....250mg (USP Specifications)	31/12/2018	26/02/2024 Slip No. 7034465127 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.
18.	TVU-4EZ-MB51	076171	Fasizol 20mg Capsule Each capsule contains: Esomeprazole (as magnesium trihydrate enteric coated pellets) eq. to Esomeprazole....40mg Manufacturer Specification **Source of Pellets:** M/s Vison Pharmaceutical Islamabad.	29/01/2014	29/02/2024 Slip No. 454077962 Rs.15000/-	Renewal is granted w.e.f 29.01.2024 to 28.01.2029. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
19.	M53-8MG-VJTU	094276	Mozole Capsule 20mg Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole....20mg (USP Specifications) **Source of Pellets:** Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	31/12/2018	26/02/2024 Slip No. 294269310339 **Rs.30000/-**	Renewal is granted w.e.f 31.12.2023 to 30.12.2028. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-

						26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
20.	TUJ-SRP-1XXQ	094270	HIPOUR TABLET 40MG Each film coated tablet contains: Febuxostat....40mg As per Innovators Specification	31/12/2018	26/02/2024 Slip No. 59475959085 Rs.30000/-	Renewal is granted w.e.f 31.12.2023 to 30.12.2028.

ii. M/s Honig Pharmaceutical Laboratories, 14 Km Adyala Road Islamabad.

21.	7HE-VEA-RRMJ	094182	Homycin Dry Suspension 125mg/5ml Each 5ml reconstituted suspension contains: Clarithromycin taste masked granules eq. to clarithromycin....125mg (USP Specifications) Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24/12/2018	22/02/2024 Slip No. 294006688 Rs. 30000/-	Renewal is granted w.e.f 24.12.2023 to 23.12.2028. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.
22.	B6Z-DTU-2JD9	094183	Homycin Dry Suspension 250mg/5ml Each 5ml reconstituted suspension contains: Clarithromycin taste masked granules eq. to clarithromycin....250mg (USP Specifications) Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24/12/2018	22/02/2024 Slip No. 8657244384 Rs. 30000/-	Renewal is granted w.e.f 24.12.2023 to 23.12.2028. Renewal letter shall be issued after approval of change of name of manufacturer of pellets vide Licensing Division Letter No. F.1-26/2009-Lic (Vol-II) dated 09.07.2018 from concerned Post Registration Variation Section.

Case No: 9 Renewal Application of Ilevro Eye Drops (Suspension) (Reg: 095874) applied by Novartis Pharma (Pakistan) Limited, 15 West Wharf Dockyard Road Karachi.

Sr. No.	Tracking ID	Reg. No.	Brand Name & Composition	date of Registration PRV(If any)	Date of application (R & I)	Decision

					Fee submitted	
1.	22V-PB3-A7JZ	095874	ILEVRO EYE DROPS (SUSPENSION) Each ml contains: Nepafenac....3mg (As per Innovators Specification) **Manufacturer:** SA Alcon-Couvreur NV Rijksweg 14,B B-2870 Puurs, Belgium **MA Holder:** Novartis Europharm Limited, Frimley Business Park, Camberley GU167SR United Kingdom.	29/05/2019	28/02/2024 Slip No. 16697229353 Rs.15000/-	Deferred for submission of notarized letter of authorization for MAH as mentioned on submitted CoPP issued by Swissmedic.

Documents required	**Documents submitted vide Dy. No. 5032 dated 16.05.2024**
The Renewal Sub Committee in its 12th meeting held on 14.03.2024 considered the reply of firm and decided that submitted response from the firm is not satisfactory. Hence the case deferred for following: i. Approval of product license holder as per submitted CoPP. ii. Clarification is required that submitted COPP bears brand Name Nevanac 3mg/ml rather Ilevro Eye Drops. iii. Legalized GMP issued by the regulatory of Belgium because as per submitted CPP the Swiss Medic is only responsible for GMP of manufactures located in Switzerland.	The submitted response as under: i. As approved MAH in registration holder, which is Novartis Pharma UK, please be informed that due the global Brexit change there was change in name & address of MAH due to which currently we cannot have CoPP with the same MAH name. Therefore, we have submitted Swiss COPP form reference country. However, we do not have approval of product License holder as per submitted new COPP for which we will submit application in DRAP for the regularization and approval of product License holder. We have already initiated requested for required documents (LoA & CoPP) along-with required fees and we will submit application as soon as we receive documents. ii. Global brand name of Ilevro is Nevanac and local brand name is Ilevro which is mentioned in submitted CoPP. iii. GMP corticated issued by Federal Agency of Medicine and Health Products Belgium is submitted.

Case No: 10 M/s. Orient Animal Health (Pvt.) Ltd Commercial # 6, Block-A, 1st Floor, Kazimabad, Model Colony Karachi

M/s. Orient Animal Health(Pvt.) Ltd Karachi has submitted an email from Univet Tullyvin Cootehill Co. Cavan, Ireland wherein the manufacturer requested for issuance of renewal of registration of below mentioned for continued supply in Pakistan as they will not be able to supply the product unless renewals are issued to them. The firm has also submitted email form manufacturer i.e., ECO Animal Health for products at 6-7, the manufacturer stated that in EU the qualified persons only release products which have active license and we are concerned that the ongoing renewal will cause an issue with the release and export of product in Pakistan. Details of the products are as under:

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg	Renewal application date (R & I) Fee submitted	Remarks

1.	048125	CURAZOLE 10% W/V ORAL DRENCH Each ml contains: Fenbendazole Ph. Eur……. 100mg **Manufacturer:** M/s Univet Tullyvin Cootehill Co. Cavan, Ireland	03/03/2008	Dy No.3742 dated:09/02/2023 Rs.30000/-	Renewal granted w.e.f 03.03.2023 to 02.03.2028 as per import policy for finished drugs.
Remarks: COPP issued by HPRA Ireland vide No. CPP-22-1217 dated 21.11.2022. Renewal letter issued to the firm vide letter F. No. 3-2/2021-RRR (M-297) dated 16.4.2021 valid till 02.03.2023.					
1.	049537	TRAMAZOLE 10% ORAL DRENCH Contains: Albendazole Ph. Eur…….100mg **Manufacturer:** M/s Univet Tullyvin Cootehill Co. Cavan, Ireland	23/07/2008	Rs.30000/- Dy No.22560 dated: 22/05/2023	Renewal granted w.e.f 03.03.2023 to 02.03.2028 as per import policy for finished drugs.
Remarks: COPP issued by HPRA Ireland vide No. CPP-23-0054 dated 11.01.2023. Renewal letter issued to the firm vide letter F. No. 3-2/2021-RRR (M-297) dated 16.4.2021 valid till 02.03.2023.					
2.	080720	UNIMOX LA INJECTION Each ml contains: Amoxicillin (as Amoxicillin Trihydrate) Ph. Eur…...150mg **Manufacturer:** M/s Univet Tullyvin Cootehill Co. Cavan, Ireland	12/05/2016	Rs.20000/- Dy No.14171 25/05/2021	Renewal granted w.e.f 12.05.2021 to 11.05.2026 as per import policy for finished drugs.
Remarks: COPP issued by HPRA Ireland vide No. CPP-21-0377 dated 27.01.2021.					
3.	081300	UNICYCLINE LA INJECTION Each ml contains: Oxytetracycline (as Oxytetracycline Dihydrate Ph. Eur) …...200mg **Manufacturer:** M/s Univet Tullyvin Cootehill Co. Cavan, Ireland	29/08/2016	Rs.20000/- Dy No.14172 25/05/2021	Renewal granted w.e.f 29.08.2021 to 28.08.2026 as per import policy for finished drugs.
Remarks: COPP issued by HPRA Ireland vide No. CPP-21-0378 dated 27.01.2021.					

4.	019956	Gentamicin Sulphate 10% Injection Each ml contains: Gentamycin Sulphate eq. to 100mg Gentamycin base **Manufacturer:** M/s. Univet Ltd., Tullyvin, Cootehill, Co. Cavan, Ireland	25-05-1997 Transfer of Registration dated: 15-11-2005	Dy. No. 30457 dated 15-01-2020 Rs. 20000/-	Keeping in view the reasons submitted on CoPP and justification provided by the firm as narrated below, Registration Board granted the renewal w.e.f. 15-11-2020 to 14.11.2025 as per import policy for finished drugs.
5.	022701	Gentamicin Sulpahte 20% Injection Each ml contains:- Gentamycin Sulphate eq. to 200mg Gentamycin Base **Manufacturer:** M/s. Univet Ltd., Tullyvin, Cootehill, Co. Cavan, Ireland	04-01-1999 Transfer of Registration dated: 15-11-2005	Dy. No. 30458 dated 15-01-2020 Rs. 20000/-	Keeping in view the reasons submitted on CoPP and justification provided by the firm as narrated below, Registration Board granted the renewal w.e.f. 15-11-2020 to 14.11.2025 as per import policy for finished drugs.
Remarks: COPP issued by HPRA Ireland vide No. CPP-19-0485 dated 03.05.2019 and CPP-19-0486 dated 03.05.2019. As per submitted CoPP, the product is not registered in country of origin reason mentioned in CoPP as "market is small and limited for this product". The firm has also submitted a notarized letter from manufacturer which states that: *"It is to bring into your kind knowledge that due to eradication of many diseases in the EU and many other countries within Europe Gentamycin 10% and 20% are no longer in so much demand in these countries. That the reason why it has been mentioned in COPP as "The Market is small and limited for this product" We have been supplying Gentamycin to Orient Animal health (Pvt) Ltd for almost 25 years and have has no issues with the product. The therapeutic spectrum for gentamycin is wide and contains Gram negative and Gram positive bacteria including Proteus mirabilis, Escherichia coli, and Staphylococcus aureus. Most of the above diseases have been eradicated in Europe so these is no longer a request for Gentamycin in Europe. All the existing European companies have found different treatments for the different disease and have a greater choice then Pakistan. Univet Ltd now produces Gentamycin for export purpose and this includes Middle East, Far East and countries such as these where the above mentioned Bacteria are a lot more prevalent. We no longer manufacturer for the local market and we have a lot of other choices treat our existing diseases".*					
6.	048126	**AIVLOSIN FG 50** **Contains:** Tylvalosin (Acetyl Isovaleryl Tylosin) Tartrate 5.0 % equivalent to Tylvalosin…..4.25 % w/w **Marketing Authorization Holder:** M/s Eco Animal Health Ltd, 78 Coombe Road, New Malden, Surrey, KT3 4QS United Kingdom **Manufacturer:** M/s. Cod Beck Blenders Limited, Cod Beck Estate Dalton Thirsk North Yorkshire YO7 3HR United Kingdom	03/03/2008	Rs.30000/- Dy No.3743 dated:09/02/2023	Renewal is granted w.e.f. 03.03.2023 to 02.03.2028 as per import policy for finished drugs.
Remarks: Veterinary Medicine Directorate UK Certificate No. 15208/22/E0338 dated 23.11.2022					

7.	048127	**AIVLOSIN SOLUBLE** (Granules for Use in Drinking Water) Contains: Tylvalosin (as Tylvalosin Tartrate)…....62.5% w/w **Marketing Authorization Holder:** M/s ECO Animal Health Ltd, 78 Coombe Road, New Malden, Surrey, KT3 4QS United Kingdom **Manufacturer:** M/s. Cod Beck Blenders Limited, Cod Beck Estate Dalton Thirsk North Yorkshire YO7 3HR United Kingdom	03/03/2008	Rs.30000/- Dy No.3748 dated:09/02/2023	Renewal is granted w.e.f. 03.03.2023 to 02.03.2028 as per import policy for finished drugs.
Remarks: Veterinary Medicine Directorate UK Certificate No. 15208/22/E0339 dated 23.11.2022					

Case No:11: Request for issuance of renewal of registration by M/s. PharmEvo (Private) Limited: A-29, North Western Industrial Zone Port Qasim Karachi

M/s. PharmEvo (Private) Limited, Karachi has requested for issuance of renewal of registration of below mentioned product for export in Mauritania. The firm has also submitted copy of purchase order as well.

Sr. No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision
276.	066841	Avsar 10/160 Tablet Each tablet contains: Valsartan… 160mg Amlodipine as Besylate… 10mg (USP Specifications)	08/10/2010	Rs.15000/- Dy No.19219 Dated 06.08.2020	Renewal is granted w.e.f. 08.10.2020 to 07.10.2025.

Item No. III. Division of Biological Evaluation & Research

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Mr. Muhammad Kashif	DD-I	51
2.	Dr. H.M Jawad Ali	DD-II	33
3.	Ms. Haleema Sharif	DD-III	12
4.	Ms. Anam Saeed	DD-IV	09
Total			**105**

CASES OF DD-I (MR. MUHAMMAD KASHIF)

Case.No.1 For information and ratification of the Registration Board.

A. Post Registration Variation cases decided in 6th PRVC for Biologicals held on 30th April,2024.

Sr. No	Applications	Decision of PRVC
1.	M/s TITLIS Pharma has applied for change of title of the Firm/Importer of M/s TITLIS Pharma (Pvt) Ltd for their following registered biological products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of name/ title of importer from M/s TITLIS Pharma Address: 528-A, Sunder Industrial Estate, Raiwind Road, Lahore to M/s TITLIS Pharma (Private) Limited Address:528-A, Sunder Industrial Estate, Raiwind Road, Lahore for the products mentioned at Sr. No. 1 to 7.
2.	M/s Hakimsons Impex (Pvt) Ltd. has applied for change of name of manufacturer (manufacturing site remains the same) & PLH and logo for their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of name/ title of Existing Name of Manufacturer & PLH from M/s Cadila Healthcare Limited Address: Sarkhej- Bavla N.H No.8-A Moraiya, Tal Sanand Ahmedabad 382210 to M/s Zydus Lifesciences Limited Address: Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No..8 A Village-Moraiya, Tal-Sanand City: Moraiya-382-210, Dist. Ahmedabad Gujrat State, India for the product Vaxirab N-Rabies Vaccine (Reg. No.106824) as per CoPP and WHO leaflet.
3.	M/s. Hilton Pharma (Pvt) Limited has applied for the change of name and address of the manufacturer of drug in exporting country.	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the new Name/ Title of Market Authorization Holder (MAH) and Manufacturer M/s PT MEDION FARMA JAYA Office Address: JI. Babakan Ciparay No.282, Kel. Babakan Ciparay, Kec. Babakan Ciparay, Bandung Indonesia and the Plant Address: JI. Raya Batujajar No.29, Cimareme, Ngamprah, Kab Bandung Barat, Indonesia and details of Brand Name and composition for the products mentioned at Sr. No.1-14 as per CoPP and GMP.
4.	M/s Lab Diagnostic Systems (SMC) Pvt Ltd has applied for change in importer's title of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of name/ title of importer from M/s Lab Diagnostic System Private Limited Plot No. 36-A, PSIC, SIE,Taxila. to M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot No. 36-A, PSIC, SIE, Taxila, for the product Pegaspargase (PEG-L Asparginase) injection (Reg. No. 105067).
5.	M/s Sanofi Aventis Pakistan Limited, Karachi applied for change in name & address of Marketing Authorization Holder of already registered products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of name/ title and address of Marketing Authorization Holder (MAH) from M/s Sanofi-Aventis Groupe 54, rue La Boetie, 75008, Paris, France to M/s Sanofi Winthrop Industrie 82, avenue Raspail, 94250, Gentilly, France for the products mentioned at Sr. No.1 & 2.
6.	M/s. Popular International (Pvt) Limited, Karachi has applied for a change of Brand Name of their already registered biological product	After detailed deliberation, on the recommendation of the Committee and keeping in view CoPP, the Chairman Registration Board Approved the change of Brand Name from Hyper Hep B S/D 0.5 mL Syringe (Reg. No. 012835) to HyperHEP B 0.5mL Syringe (Reg. No. 012835) manufactured by M/s Grifols Therapeutic LLC., 8368-US 70 Bus Hwy W, Clayton, NC 27520, USA and Market Authorization Holder (MAH) M/s Grifols Therapeutic LLC., 79 T.W. Alexander Dr. 4101 Research Commons, Research Triangle Park, NC 27709, USA.

7.	M/s A.J.Mirza Pharma (Pvt) Ltd., Karachi. Pakistan has applied on 26-06-2023 for the transfer of registration/ change of importer /Change of Importer from M/s AA Pharma to M/s A.J.Mirza Pharma (Pvt) Ltd of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board deferred the case and advised to issue show cause notice under section 42 of the Drugs Act, 1976 to M/s AA Pharma 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan, as the Market Authorization Holder has terminated their Sole Agency Agreement for the products mentioned at Sr. No.1 & 3 and give them personal Hearing for transfer of their above mentioned products to M/s A.J. Mirza Pharma (Pvt) Ltd Address:1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan in the light of their NOC for the transfer.
8.	M/s HUZAIFA INTERNATIONAL has applied for Extension of shelf life of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided as under: a. Deferred the cases for verification of registration numbers issued to the products at serial number 1 to 3 and also place complete list of products before PRVC, registered with this number format. b. Application for renewal of Registration of product PRO-VAC NDK (Reg. No. 077519) was submitted after due date but within sixty days. Hence the committee refer the case to Registration Board for regularization of registration of product PRO-VAC NDK (Reg. No. 077519).
9.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the update in product specifications of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Decided as under: 1. Approved Ph. Eur. Specs for the products mentioned at Sr. No. 2,4, 5 & 6. 2. Not acceded to the request of the firm for the products mentioned at Sr. No. 1 & 3, as the change in manufacturing site of the same products has already been approved by the Registration Board in its 332nd Meeting.
10.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the inclusion of shelf life of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the shelf life of 30 months (2-8 ºC) and storage details as per CoPP for the products mentioned at Sr. No. 1 to 2.
11.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for inclusion of the shelf life of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided as under: a. Approved the shelf life of 24 months (2-8 ºC) and storage details as per CoPP for the product mentioned at Sr. No. 1. b. Approved the shelf life of 30 months (2-8 ºC) and storage details as per CoPP for the product mentioned at Sr. No. 2.
12.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the update in shelf life with storage conditions of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided as under: 1. Approved the shelf life of 30 months (2-8 ºC) of the products mentioned at Sr. No. 2 & 4. 2. Not acceded to the request for the products mentioned at Sr. No. 1 & 3, as the change in manufacturing site of the same products has already been approved by the Registration Board in its 332nd Meeting.
13.	M/S HIPRA Pakistan have submitted the application applied for the addition of solvent part to their already	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board approved the composition of the products as per FSC and addition of solvent with composition mentioned in Column No. 5 of the above table for the products mentioned at Sr. No. 1 to 4.

	registered biologicals products	
14.	M/s. Macter International Limited, has applied for change of name /Title of Bulk Manufacturer (Manufacturing site remains the same) of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of name of Bulk manufacturer from M/s Shandong Kexing Bio Product Co., Limited Address no. 2666 Chuangye Road, Mingshui Development Zone, Zhangqiu Shandong, China to M/s Kexing BioPharm Co., Limited" Address no. 2666 Chuangye Road, Bucun Sub district, Zhangqiu, Jinan, Shandong, China for the products mentioned at Sr. No.1 to 3.
15.	M/s BF Biosciences Limited has request to issue Corrigendum for mentioning "Source of API" of Filgen Injection in the registration letter	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board Approved the change of source of Bulk from M/s Bioprofarma S.A., Argentina to M/s Gemabiotech S.A.U Fray Justo Sarmiento 2350 (Zip Code B1636AKJ- Olivos. Bs As, Argentina) for the product Filgen (Filgrastim) 30MIU Injection (Reg. No. 028726).

B. Post Registration Variation cases decided in 7th PRVC for Biologicals held on 17th May, 2024.

Sr. No.	Applications	Decision of PRVC
16.	M/s Hipra Pakistan (Pvt) Ltd has applied for change of address of Firm/Importer for their following registered biological products	After detailed deliberation and keeping in view letter of authorization issued by MA Holder i.e. M/s Laboratorios Hipra, SA Avda. La Salva Spain and on the recommendation of the Committee, the Chairman Registration Board: - i. Acceded to request of firm for change of address of importer from M/s Hipra Pakistan (Pvt) Ltd Office Address:3rd Floor, Plot No. 8, Block CCA, Phase 6-C, D.H.A., Lahore. Warehouse Address:2nd warehouse on left side, street no 5, Gajjumata, Nadir Chowk, Hazara Chowk, Industrial Area, Ferozepur Road, Lahore to M/s Hipra Pakistan (Pvt) Ltd Office & Warehouse Address: House No. 86-88, J-1, Sunflower Society, M.A Johar Town, Lahore for the products mentioned at S. No 1-30 & 32-35. ii. Defer the products HIPRAPOX Vaccine 1000 ds for submission of letter of authorization by the MA holder.
17.	M/s Getz Pharma (Pvt) Ltd has applied for change of specifications for their already registered Biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board deferred the case for clarification of the Biological section of M/s Getz Pharma (Pvt) Ltd. from Licensing Division.
18.	M/s Helix Pharma (Pvt)., Ltd, A-56, S.I.T.E, Karachi, Pakistan, has applied for shelf-life extension from 24 months to 36 months for their already registered biological drug	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board defer the case for submission of stability data with legalized evidence of approval of extension in shelf life in country of origin.
19.	M/s Lab Diagnostic Systems SMC Pvt Ltd has applied for change in brand name of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board acceded to request of the firm for change of brand name from *"Pegaspargase (PEG-L-Asparginase) injection"* to "*Pegaspa Injection"*.

20.	M/s. OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi, having valid DSL No:024, applied for the ***change Importer in Pakistan***.	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board deferred the case for personal hearing to M/s Hakimsons (impex) (Private) Ltd., Hakimson building, 19 West Wharf Road Karachi, under section 42 of the Drugs Act, 1976. As the Market Authorization Holder has terminated their Sole Agency Agreement for the products mentioned at Sr. No.49 & 50 for transfer of their above mentioned products to M/s OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi.
21.	M/s Barrett Hodgson Pakistan (Pvt) Ltd. has applied for change of Marketing Authorization Holder of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board acceded to request of the firm for change of Marketing Authorization Holder of Botox (Botulinum Toxin Type A) Vial, Registration No. 018959 from *"M/s Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Irelan"* to *"M/s AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland'* for the products mentioned at Sr. No. 52.

Decision: The Board ratified all the above decisions of the PRVC.

Export cases deferred in 335th R.B Meeting

These cases were evaluated by the working group comprising of Mr. Muneeb Ahmed Cheema (Deputy Director PE&R), Mr. Muhammad Kashif (Deputy Director BE&R):

Case No.2: Registration of Drug (s) of M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hatter for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided Approval of relevant section verified from Licensing Division Letter No. F. 3-6/2007-Lic (Vol-II) dated 25-10-2023.
GMP Status. Copy of Inspection report/GMP certificate.	New Section is approved on 25-10-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
1	Semggo 3mg Tablet Each uncoated tablet contains: Semaglutide…….3mg	Rybelsus of Novo Nordisk	Dy. No. 1703 (08.12.2023) Rs.30, 000/- 15.11.2023)

2	Semggo 7mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1704 (08.12.2023) Rs.30, 000/- 15.11.2023
3	Semggo 14mg Tablet Each uncoated tablet contains: Semaglutide…….14mg	Rybelsus of Novo Nordisk	Dy. No. 1702 (08.12.2023) Rs.30, 000/- 15.11.2023

Previous Remarks:

The case was evaluated and the deficiency letter has been issued with following requirements:

i. Valid GMP certificate of Source of API is required.
ii. Manufacturing process and Analytical procedures of Semaglutide (API) is required as it is a biological product.
iii. Salcaprozate sodium is used in the formulation which is a novel excipient. So, details regarding its manufacturer, process and method validations and certificate of analysis is required.
iv. Complete descriptions of the specifications and analytical methods of the Finished product is required including test for assay of Salcaprozate sodium in Semaglutide tablet.
v. Form 5 is a part of Drugs (Licensing, Registering and Advertising) Rules, 1976 and its format and title cannot be changed. So properly filled and signed Form 5 is required in its actual format.
vi. The brand name mentioned on affidavit of SEMGGO 14mg Tablet is incorrect.
vii. The fee challans of all three products are paid under the head of Pharmaceutical Evaluation and Registration while these are biological products.

Decision of 335th R.B Meeting: *The Board after detailed deliberation decided to defer the applications for submission of required documents.*

Now the firm has submitted following documents:

Sr. No.	Queries	Reply
1.	Valid GMP certificate of Source of API is required.	Audit Evaluation report of GMP certification in Guangdong Province issued by Qingyuan City Qingcheng Distruct Shijiao Industrial Park Management Committee dated 01.0.2022 for M/s Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.
2.	Manufacturing process and Analytical procedures of Semaglutide (API) is required as it is a biological product.	The firm has submitted the Manufacturing process, BMR and specifications including analytical procedures of finished product.
3.	Salcaprozate sodium is used in the formulation which is a novel excipient. So, details regarding its manufacturer, process and method validations and certificate of analysis is required.	Certificate of analysis issued by Gansu Haotian Pharma Tech Co., Ltd Gansu China dated 19.05.2023 is submitted along with proposed specification and analytical procedures by the manufacturer
4.	*Complete descriptions of the specifications and analytical methods of the Finished product is required including test for assay of Salcaprozate sodium in semaglutide tablet.*	The firm has submitted proposed specifications for finished product along with method testing including the assay limits for *Salcaprozate sodium* by Gansu Haotian Pharma Tech Co., Ltd Gansu China.
5.	*Form 5 is a part of Drugs (Licensing, Registering and Advertising) Rules, 1976 and its format and title cannot be changed. So properly filled and signed Form 5 is required in its actual format.*	Revised Form-5 is submitted.

6.	*The brand name mentioned on affidavit of SEMGGO 14mg Tablet is incorrect.*	Revised document with correct name is submitted.
7.	*The fee challans of all three products are paid under the head of Pharmaceutical Evaluation and Registration while these are biological products.*	Fee Rs.75000/- each dated 23.04.2024 is submitted under the head of BE&R

Decision: The Board after detailed deliberation decided to approve Semggo 3mg Tablet, Semggo 7 mg Tablet and Semggo 14mg Tablet for export purpose only. The firm will submit the manufacturing process in detail.

Case No.3: Registration of Drug (s) of M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar manufactured by M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hatter on contract manufacturing for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided Approval of relevant section of M/s Weather Folds verified from Licensing Division Letter No. F. 3-6/2007-Lic (Vol-II) dated 25-10-2023.
GMP Status. Copy of Inspection report/GMP certificate.	New Section is approved on 25-10-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
1	Maglu 3mg Tablet Each uncoated tablet contains: Semaglutide…….3mg	Rybelsus of Novo Nordisk	Dy. No. 1701 (08.12.2023) Rs.30, 000/- 15.11.2023)
2	Maglu 7mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1700 (08.12.2023) Rs.30, 000/- 15.11.2023
3	Maglu 14mg Tablet Each uncoated tablet contains: Semaglutide…….14mg	Rybelsus of Novo Nordisk	Dy. No. 1699 (08.12.2023) Rs.30, 000/- 15.11.2023

Remarks:

The case was evaluated and the deficiency letter has been issued with following requirements:

i. Contract/Agreement with M/s Weather Folds for Toll manufacturing is not provided.
ii. Valid GMP certificate of Source of API is required.
iii. Manufacturing process and Analytical procedures of Semaglutide (API) is required as it is a biological product.
iv. Salcaprozate sodium is used in the formulation which is a novel excipient. So, details regarding its manufacturer, process and method validations and certificate of analysis is required.

v. Complete descriptions of the specifications and analytical methods of the Finished product is required including test for assay of Salcaprozate sodium in semaglutide tablet.
vi. Form 5 is a part of Drugs (Licensing, Registering and Advertising) Rules, 1976 and its format and title cannot be changed. So properly filled and signed Form 5 is required in its actual format.
vii. The brand name mentioned on affidavit of MEGLU 14mg Tablet is incorrect.
viii. The fee challans of all three products are paid under the head of Pharmaceutical Evaluation and Registration while these are biological products.

Decision of 335th R.B Meeting: The Board after detailed deliberation decided to defer the applications for submission of required documents.

Submitted in the light the reply of M/s Weather Folds Pharmaceuticals:

Decision: **The Board after detailed deliberation decided to approve Maglu 3mg Tablet, Maglu 7mg Tablet and Maglu 14mg Tablet** to **M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar manufactured by M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hatter on contract manufacturing for export purposes only subject to submission of agreement of contract manufacturing. The firm will submit the manufacturing process in detail**

New cases of Export registration;

Case. No.4. M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi for export purposes only.

Requirements as per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided. Approval of section vide Licensing Division Letter No. F. 2-14/85-Lic (Vol-VI) dated 14.02.2024
GMP Status	GMP Inspection by area FID dated 01.09.2023, operating at appropriate compliance GMP certificate issued by DRAP Karachi dated: 24.01.2024
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr. No.	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Dy. No. (EFD)/Fee with date**
I	**II**	**III**	**IV**
1	**Semhil Tablets 3mg** Each tablet contains: Semaglutide …..... 3mg	SEMAGLUTIDE 3MG TABLETS Rybelsus 3mg Tablet, Manufactured by Novo Nordisk A/S, Denmark (FDA Approved)	TID: T8L-3QH-N3M9 Registration Fee of Rs. 30,000 dated: 26-04-2024 Paid Slip # 903109507471
2	**Semhil Tablets 7mg** Each tablet contains: Semaglutide …..... 7mg	SEMAGLUTIDE 7MG TABLETS Rybelsus 7mg Tablet, Manufactured by Novo Nordisk A/S, Denmark (FDA Approved)	TID: 4G4-4TN-4BJN Rs. 30,000 dated: 26-04-2024 Paid Slip #1558999486

3	**Semhil Tablets 14mg** Each tablet contains: Semaglutide …..... 14mg	SEMAGLUTIDE 14MG TABLETS Rybelsus 14mg Tablet, Manufactured by Novo Nordisk A/S, Denmark (FDA Approved)	TID: 6LV-1E2-PUAH Registration Fee of Rs. 30,000 dated: Paid Slip #9102443335

Source of Semaglutide API:
M/s Sinipep Allsino Biopharmaceutical Co., Limited, No. 28, Linpu Road, Economic and Technological Development Zone, Lianyungang, Jiangsu, China.

GMP Status of API Manufacturer:
GMP certificate issued on 24.01.2023 issued by Lianyungang Pharmaceutical Association.

Source of Salcaprozate Sodium:
M/s Jiangsu Souteast Nanomaterials Co., Ltd., No. 15, Basi Road, Jinhu Contry, Huai'an City, Jiangsu, China

GMP Status of Salcaprozate Sodium:
GMP certificate issued on 05.12.2020 issued by Huai'an Pharmaceutical Association

Export Order:
Copy of Export Order for the market of the Customs Union and the Common Economic Space of the countries participating in the Eurasian Economic Union (EAEU): Kazakhstan, Russia, Belarus, Armenia, Kyrgyzstan and Uzbekistan.

Decision: The Registration Board after detailed deliberation decided to approved subject to the submission of the GMP Certificate from the Authority of China.

Case.No.5. M/s. Hilton Pharma (Pvt.) Ltd., Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi for export purposes only.

Requirements as per SOP	**Submitted Documents**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided. Approval of relevant section vide Licensing Division Letter No. F.2-5/85-Lic (Vol iv) dated 30.06.2020
GMP Status.	GMP Inspection by area FID dated 01.09.2023, operating at appropriate compliance GMP certificate issued by DRAP Karachi dated: 24.01.2024
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr. No.	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Dy. No. (EFD)/Fee with date**
I	**II**	**III**	**IV**
32.	**Semhil Injection 1.7mg/0.75ml** Each 0.75mL contains: Semaglutide.....1.7mg	SEMAGLUTIDE 1.7MG/0.75ML INJECTION Wegovy, manufactured by Novo Nordisk Inc	TID: 4Y4-HDY-LBVB Registration Fee of Rs. 75,000 dated: 02-05-2024 Paid Slip # 4120387419

		(FDA Approved)	
33.	**Semhil Injection 2.4mg/0.75mL** Each 0.75mL contains: Semaglutide ……. 2.4mg	SEMAGLUTIDE 2.4MG/0.75ML INJECTION Wegovy, manufactured by Novo Nordisk Inc (FDA Approved)	TID: ALU-QVW-1Y29 Registration Fee of Rs. 75,000 dated: 02-05-2024 Paid Slip # 29479008
34.	**Semhil Injection 0.5mg/0.5mL** Each 0.5mL contains: Semaglutide ……. 0.5mg	SEMAGLUTIDE 0.5MG/0.5ML INJECTION Wegovy, manufactured by Novo Nordisk Inc (FDA Approved)	TID:2BM-P2U-HZUZ Registration Fee of Rs. 75,000 dated: 26-04-2024 Paid Slip # 448095688178
35.	**Semhil Injection 0.25mg/0.5mL** Each 0.5mL contains: Semaglutide ……. 0.25mg	SEMAGLUTIDE 0.25MG/0.5ML INJECTION Wegovy, manufactured by Novo Nordisk Inc (FDA Approved)	TID: 34T-GDP-AAUY Registration Fee of Rs. 75,000 dated: 26-04-2024 Paid Slip # 9542536858
36.	**Semhil Injection 1mg/0.5mL** Each 0.5mL contains: Semaglutide ……. 1mg	SEMAGLUTIDE 1MG/0.5ML INJECTION Wegovy, manufactured by Novo Nordisk Inc (FDA Approved)	TID: ANY-L8S-1SV1 Registration Fee of Rs. 75,000 dated: 26-04-2024 Paid Slip # 1053257977
37.	**Semhil Injection 2mg/1.5mL** Each mL contains: Semaglutide ……. 1.34mg	SEMAGLUTIDE 2MG/1.5ML INJECTION Ozempic, manufactured by Novo Nordisk Inc (FDA Approved)	TID:RT6-SSX-NUGH Registration Fee of Rs. 75,000 dated: 26-04-2024 Paid Slip # 008729683623
38.	**Semhil Injection 2mg/3mL (0.68mg/mL)** Each mL contains: Semaglutide ……. 0.68mg	SEMAGLUTIDE 2MG/3ML INJECTION Ozempic, manufactured by Novo Nordisk Inc (FDA Approved)	TID: 1JJ-VJ4-TAWD Registration Fee of Rs. 75,000 dated: 02-05-2024 Paid Slip # 44993579
39.	**Semhil Injection 4mg/3mL** Each mL contains: Semaglutide ……. 1.34mg	SEMAGLUTIDE 4MG/3ML INJECTION Ozempic, manufactured by Novo Nordisk Inc (FDA Approved)	TID:8J1-U87-HD2D Registration Fee of Rs. 75,000 dated: 26-04-2024 Paid Slip # 88909876
40.	**Semhil Injection 8mg/3mL (2.68mg/mL)** Each mL contains: Semaglutide ……. 2.68mg	SEMAGLUTIDE 8MG/3ML INJECTION Ozempic, manufactured by Novo Nordisk Inc (FDA Approved)	TID: 5L6-N9A-8ZMA Registration Fee of Rs. 75,000 dated: 02-05-2024 Paid Slip # 313543514139

Source of API:

M/s Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.

Remarks:

i. The submitted copy of GMP Certificate is issued by China National Association of Pharmaceutical and Medical Equipment Industry Technical Market, China.

ii. Copy of Export Order for the market of the Customs Union and the Common Economic Space of the countries participating in the Eurasian Economic Union (EAEU): Kazakhstan, Russia, Belarus, Armenia, Kyrgyzstan and Uzbekistan.

Decision: The Registration Board after detailed deliberation decided to approved subject to the submission of the GMP Certificate from the Authority of China.

Case.No.6. Registration of Drug (s) of M/s Nextar Pharma Pvt Ltd, Plot No, E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5D
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel Inspection Report dated 22-03-2023
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 20-05-2021. GMP Receiving date: 17-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
41.	Sematide Solution for Injection 0.25mg/0.5ml Pre- filled Syringe Each 0.5mL contains: Semaglutide…….0.25 mg	Not Available	RRT-WQP-QPRZ dated 2024-04-02 Fee submitted Rs. 75,000/- Sip No.64730047518
42.	Sematide Solution for Injection 0.5mg/0.5ml Pre- filled Syringe Each 0.5mL contains: Semaglutide…….0.5mg	Not Available	RXT-6MW-4GJ7 dated 2024-04-02 Fee submitted Rs. 75,000/- Sip No.7854134199
43.	Sematide Solution for Injection 1.7mg/0.75ml Pre- filled Syringe Each 0.75mL contains: Semaglutide…….1.7mg	Not Available	Z9Q-LVN-N79V dated 2024-04-02 Fee submitted Rs. 75,000/- Sip No.48533009186
44.	Sematide Solution for Injection 1mg/0.5ml Pre- filled Syringe Each 0.5mL contains: Semaglutide…….1mg	Not Available	7Y4-3ST-G1YZ dated 2024-04-02 Fee submitted Rs. 75,000/- Sip No.527385558880
45.	Sematide Solution for Injection 2.4mg/0.75ml Pre-filled Syringe Each 0.75mL contains: Semaglutide…….2.4mg	Not Available	3DM-URJ-T13D dated 2024-04-02 Fee submitted Rs. 75,000/- Sip No.33178876
Source of Bulk: M/s Nanjing Hanxin Pharmaceutical Technology Co., Ltd., Building C5, No.9 Weidi Road, Xianlin University Town, Xianlin Street, Qixia District, Nanjing City, Jiangsu Province, China 210046. **Manufacturing Address;** No.5 Xinghe Road, Nanjing Economic and Technological Development Zone Jiangsu, China 210038			

Remarks:

i. The submitted copy of GMP Certificate is issued by Nanjing Pharmaceutical Quality Management Association, China
ii. Copy of Export Order from M/s World Health Pharmaceutical Co.,Ltd ,Cambodia is submitted.

Decision: The Registration Board after detailed deliberation decided to approve subject to the submission of the GMP Certificate from the Authority of China.

CASES OF DD-II (Dr. H.M. JAWAD ALI)

Following product of M/s Grand Pharma Pvt. Ltd., Lahore was considered in 324th meeting of Registration Board as per following details;

52.	**Name and address of product manufacturer (Applicant)**	**M/s Grand Pharma Pvt Ltd** Plot # 5-A, Street No.N-5, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Vaxi-drop (0.30ml per bird)
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.20999 Date:21-8-2020 Rs. 20,000/- Date: 19-8-2020
	Composition	Each ml contains: Monobasic Potassium Phosphate: ……0.37 mg Disodium Phosphate Dihydrate:…… 0.72 mg Sodium Chloride : ……...7.65mg
	Pharmacological Group	Diluent for live Avian vaccines
	Finished Product Specification	Manufacturer' Spec
	Shelf Life	2 Years (15°C -25°C)
	Document Details	All the undertaking has been submitted by the firm. Copy of DML Copy of inspection report for GMP for viral vaccines section (killed) & Bacterial killed vaccine section.
	Pack size & Demanded Price	1000ml**; Decontrolled**
	Products already registered in Pakistan	*MS Bac* (M/s Hi-Tech Pharma, Lahore)
	Remarks of Evaluator	

Registration Board in its 324th meeting decided as under:

"Registration Board deferred the case and advised to deliberate the case with Licensing Division regarding manufacturing requirements of diluents for vaccine"

The firm has submitted response wherein they have mentioned that earlier approved packing (36ml) of this product is manufactured in "**Killed Bacterial vaccine section**" at Grand pharma production unit. The newly proposed packing of 1L will also be manufactured in Killed bacterial vaccine section where a filling line for packing of 1 Liter bottles already exists.

In view of decision of Registration Board and response by the firm, the case was forwarded to licensing division for their comments / input on the matter for further processing of the case.

Comments of Licensing Division:

"It is submitted that the FID-I Islamabad pointed out in her inspection report dated 16th June 2022 of M/s Amson Vaccines & Pharma (Pvt) Ltd, 113 Industrial Triangle Kahuta Road that the firm was carrying out manufacturing of Water for Injection 2ml in Vaccine section and Registration Board in its 342thmeeting considered the case and decided as under:

"*Suspension of Registration of "Water for injection 2ml registration No.024873" of M/s Amson Vaccines Pharma till establishment and approval of separate section by Licensing Division, DRAP for manufacturing of this product with immediate effect."*

The manufacturing of any drug other than vaccine cannot take place in Vaccine manufacturing area. However, M/s Grand Pharma (Pvt) Ltd, Rawat, has a Liquid Injectable (Vial) (General) (Veterinary) Section and Registration Board may consider request for registration of Vaxi-drop of provided the firm possesses the necessary facilities to do so. The same information may be shared with concerned quarters, please.**"**

Decision: The board deliberated the matter and decided as under: -

I. The Board Authorized Director BER to nominate a panel to visit M/s Grand Pharma (Pvt.) Ltd., Rawat, to verify the facility of Liquid Injectable (Vial) (General) (Veterinary) Section for "One Little pack size" subject diluent.
II. The registration letter will be issued after verification.

IMPORT OF VETERINARY BIOLOGICAL DRUGS.

53.	Name & address of Importer	M/s Forward Solutions, Plot No. 19-B, Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore.
	Detail of DSL	M/s. Forward Solutions Address: Plot No. 19-B, Abdul Sattar Edhi Road, Near Qazalbash Chowk, Lahore. DSL No. 05-352-0066-028137D Valid till 10-Feb-2029
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Name & address of Manufacturer	M/s Fatro S.p.A – Italy Address: Via Molino Emili, 2 – 25030 Maclodio, Brescia, Italy.
	Name & address of MAH/ Product Licence Holder	M/s Fatro S.p.A – Italy Address: Via Emilia, 285 – 40064 Ozzano Emilia Bolgna, Italy.
	Name of exporting country	**Italy (Approved in EMA** MS-H Vaccine | European Medicines Agency (europa.eu)**)**
	Dy. No. and date of submission	Dy. No. 28389 dated 06/10/2022
	Details of fee submitted	PKR 150,000/-: dated 06/10/2022
	The Brand Name + Dosage Form	MS-VAC (Emulsion for injection)
	Composition	Active ingredients and amount per unit dose: Inactivated culture of *Mycoplasma synoviae* ……..1× 10^{10} CFU; Before inactivation to induce protection to experimental infection not less than 70%.
	Pharmacological Group	Biologicals
	Type of Form	Form 5A
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	250 ml (500 doses vial)
	Document Details	**Legalized GMP** GMP certificate granted on 18-05-2022 Valid till: 08-04-2025 **Legalized Original CoPP** Firm has submitted Certificate of Pharmaceutical Product confirming that product is in the markets of exporting country and plant and facilities conform to the Good manufacturing practices in force within the European community **Sole Agency Authorization Letter:** Firm has submitted the Sole Agency Authorization Letter from M/s Fatro S.p.A (Italy) to M/s Forward Solutions (Lahore-Pakistan)
	Shelf – Life	**24 Months** Firm has submitted the stability studies of three batches at (2°C - 8°C) for 27 months.
	Reference Regulatory Authority	Registered in Italy (Reg no. 100122)

Remarks OF Evaluator: The application has been evaluated and shortcomings communicated vide lette no. No.F.3-58/2015-DDC-(BD) (Vol-I) Dated 27-05-2024 as follows: In Stability studies data it is mentioned that "No In-use stability studies performed so vial should be used immediately after opening the bottle", while the leaflet claims that 'use within 24-hours after opening the bottle' clarification/ correction is required.		
Decision: Keeping in view legalized CoPP indicating product availability in country of origin and approval of Italy (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
54.	Name & address of Importer	M/s Forward Solutions, Plot No. 19-B, Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore.
	Detail of DSL	M/s. Forward Solutions Address: Plot No. 19-B, Abdul Sattar Edhi Road, Near Qazalbash Chowk, Lahore. DSL No. 05-352-0066-028137D Valid till 10-Feb-2029.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Name & address of Manufacturer	M/s Fatro S.p.A – Italy Address: Via Molino Emili, 2 – 25030 Maclodio, Brescia, Italy.
	Name & address of MAH/ Product Licence Holder	M/s Fatro S.p.A – Italy Address: Via Emilia, 285 – 40064 Ozzano Emilia Bolgna, Italy.
	Name of exporting country	**Italy (Approved in EMA** MS-H Vaccine | European Medicines Agency (europa.eu)**)**
	Dy. No. and date of submission	Dy. No. 28388. dated 06/10/2022
	Details of fee submitted	PKR 150,000/-: dated 06/10/2022
	The Brand Name + Dosage Form	MYC-VAC (Emulsion for injection)
	Composition	Active ingredients and amount per unit dose: Inactivated *Mycoplasma gallisepticum* not less than…….. 3×10^{10} CFU
	Pharmacological Group	Biologicals
	Type of Form	Form 5A
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	250 ml (500 doses vial)
	Document Details	**Legalized GMP** GMP certificate granted on 18-05-2022 Valid till: 08-04-2025 **Legalized Original CoPP** Firm has submitted Certificate of Pharmaceutical Product confirming that product is in the markets of exporting country and plant and facilities conform to the Good manufacturing practices in force within the European community **Sole Agency Authorization Letter:**

		Firm has submitted the Sole Agency Authorization Letter from M/s Fatro S.p.A (Italy) to M/s Forward Solutions (Lahore-Pakistan)
	Shelf – Life	**24 Months** Firm has submitted the stability studies of three batches at (2°C - 8°C) for 27 months
	Reference Regulatory Authority	Registered in Italy (Reg no. 102336)

Remarks OF Evaluator: The application has been evaluated and shortcomings communicated vide lette no. No.F.3-58/2015-DDC-(BD) (Vol-I) Dated 27-05-2024 as follows:
In Stability studies data it is mentioned that "No In-use stability studies performed so vial should be used immediately after opening the bottle", while the leaflet claims that 'use within 24-hours after opening the bottle' clarification/ correction is required.

Decision:
Keeping in view legalized CoPP indicating product availability in country of origin and approval of Italy (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

55.	Name of Importer	M/s Hivet Animal Health Business, Lahore 1st. Floor,667-P. MA, Johar Town, Lahore, Pakistan
	DSL details	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028.
	Marketing authorization holder	PT. VAKSINDO SATWA NUSANTARA Wisma Millenia, Jl. MT Haryono Kav. 16 Jakarta- Indonesia.
	Name of Manufacturer	PT. VAKSINDO SATWA NUSANTARA JI. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name +Dosage Form + Strength	VAKSIMUNE ND Inaktif VaksimuneND Inaktifis an inactivated vaccine of Newcastle Disase virus of LaSotastrain, in the form of oil emulsion
	Diary No. Date of R& I & fee	Dy. No. 1186 date of submission; 13/1/ 2022 Challan no. 182725875 Dated' 19/12/2022, Rs.150,000
	Composition	Each dose contain: Active substances: - NDvirus of the LaSota strain, inactivated Virus titer (pre inactivation) is at least..... $10^{8.3}$ EID_{50}
	Pharmacological Group	Inactivated Emulsified veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	1000 dose vial (500ML) / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Evidence of same formulation already registered in Pakistan. Product Applied: (Vaksimune ND Inaktif) Already Approved Same Product: Brand Name: (Medivac ND Emulsion) Pak Reg No. 033211 Pack Size: 500ML Name of Importer: Hilton pharma (Not matched)

	Stability data of finished product	The firm has submitted stability study data of 24 months conducted at 2°C to 8°C for three consecutive batches as below: B01AM1800V B01AM19OOA B01AM19OOK
	Document Details	• Legalized FSC issued on March 31, 2022 issued by Ministry Of Agriculture, Directorate General Of Livestock And Animal Health Services. • Legalized Copy of GMP • Legalized Copy of Manufacturing License. • Legalized Copy of Last Inspection Report. • Legalized Authorization Letter
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • FSC does not contains the composition of the applied product. • Mention complete address of the manufacturing site at the label of subject product. • The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is reqd. • Provide the particular me too/generic status. • Pertinently, another firm importing the same class of products from same manufacturer but there is difference of 'live' and 'killed' vaccines.	
	Decision: The registration board deferred the case for submission of following deficiencies. • **Submission of FSC showing the composition of the applied product.** • **Revision of Label mentioning complete address of the manufacturing site at the label.** • **The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed**	
56	Name of Importer	M/s Hivet Animal Health Business, Lahore 1st. Floor,667-P. MA, Johar Town, Lahore, Pakistan
	DSL details	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Marketing authorization holder	PT. VAKSINDO SATWA NUSANTARA Wisma Millenia, Jl. MT Haryono Kav. 16 Jakarta- Indonesia.
	Name of Manufacturer	PT. VAKSINDO SATWA NUSANTARA JI. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name +Dosage Form + Strength	VAKSIMUNE ND IB Inaktif VaksimuneND IB Inaktifis a combined inactivated vaccine of Newcastle Disease (ND) LaSota strain and Infectious Bronchitis (IB) Massachusetts-41 strain in oil emulsion..
	Diary No. Date of R& I & fee	Dy. No. 1185 date of submission; 13/1/ 2022 Challan no. 1310505014 Dated' 19/12/2022, Rs.150,000
	Composition	Each dose contain: Active substances: - NDvirus of the LaSota strain, inactivated Virus titer (pre inactivation) is at least …..... 108.3 EID50 - IB virus of Massachusetts - 41 strain, inactivated. Virus titer (pre inactivation) is at least ……..... 107.0 EID50 Excipients: - Adjuvant (Liquid paraffin, Sorbitan Sesquioleate, Polyoxyethylene 20 Sorbitan Monooleate)…….....…..... - Formalin.....… 0.35 0.2 ml %
	Pharmacological Group	Inactivated Emulsified veterinary vaccine
	Type of Form	Form-5A

	Finished Product Specification	Manufacturer's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	1000 dose vial (500ML) / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Evidence of same formulation already registered in Pakistan . Product Applied : (Vaksimune ND IB Inaktif.) Already Approved Same Product : Brand Name:(Nobilis IB+ND) Pak Reg No. 010738 Pack Size: 500ML Name of Importer: Vety Care Pvt. Ltd. Brand Name :(Gallimune) Pak Reg No. 034559 Pack Size: 300ML Name of Importer: Sadaat International.
	Stability data of finished product	The firm has submitted stability study data of 24 months conducted at 2°C to 8°C for three consecutive batches as below: B04AM1800V B04AM19OOA B04AM19OOK
	Document Details	• Legalized FSC issued on March 31, 2022 issued by Ministry of Agriculture, Directorate General of Livestock And Animal Health Services. • Legalized Copy of GMP • Legalized Copy of Manufacturing License. • Legalised Copy of Last Inspection Report. • Legalised Authorization Letter
	Remarks OF Evaluator: The application has been evaluated and shortcomings communicated vide letter no. No.F.3-58/2015-DDC-(BD) (Vol-I) Dated 30-05-2024 as follows: • FSC does not contains the composition of the applied product. • Mention complete address of the manufacturing site at the label of subject product. • The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is reqd. • Provide the particular me too/generic status. • Pertinently, another firm importing the same class of products from same manufacturer but there is difference of 'live' and ;killed' vaccines.	
	Decision: <u>The registration board deferred the case for submission of following deficiencies;</u> • **Submission of FSC showing the composition of the applied product.** • **Revision of Label mentioning complete address of the manufacturing site at the label.** • **The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is reqd.**	

57.	Name of Importer	M/s Hivet Animal Health Business, Lahore 1st. Floor,667-P. MA, Johar Town, Lahore, Pakistan
	DSL details	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Marketing authorization holder	PT. VAKSINDO SATWA NUSANTARA Wisma Millenia, Jl. MT Haryono Kav. 16 Jakarta- Indonesia.

	Name of Manufacturer	Plant Address: PT. VAKSINDO SATWA NUSANTARA JI. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, ~~West Java~~ 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name +Dosage Form + Strength	VAKSIMUNE CORYZA COLI Combination of Avibacterium Paragallinarum serotype A 0083-strain, serotype B-V5 strain, serotype C Modesto and V-26 strain and E.coli serotypes O1K1, O2K1, and O78K80. (Inactivated Vaccine In oil Emulsion).
	Diary No. Date of R& I & fee	Dy. No. 27147 date of submission; 26 September 2022 Challan no. 190576478169, Dated' 08/09/2022, PKR.150,000/-
	Composition	Each dose contains: - Avibacterium paragallinarum serotype A strain 0083, (pre-inactivation) is at least ..... $10^{8.0}$ CFU - Avibacterium paragallinarum serotype B local isolat, strain V5, (pre-inactivation) is at least ..... $10^{8.5}$ CFU - Avibacterium paragallinarum serotype C, strain Modesto, (pre-inactivation) is at least ..... $10^{8.0}$ CFU - Avibacterium paragallinarum serotype C local isolat, strain V26, (pre-inactivation) is at least ..... $10^{8.5}$ CFU - Escherichia coli serotype O1K1, (pre-inactivation) is at least ..... $10^{9.0}$ CFU - Escherichia coli serotype O2K1, (pre-inactivation) is at least ..... $10^{9.0}$ CFU - Escherichia coli serotype O78K80, (pre-inactivation) is at least ..... $10^{9.0}$ CFU
	Pharmacological Group	Inactivated Emulsified veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specification
	Shelf Life	24-months (2°C-8°C)
	Pack size and demanded price	1000 dose vial (500ML) / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	1-Already Approved Same Antigen Product For Coryza: Brand Name:(Haemovax) Pak Reg No. 011485 Pack Size: 300ML Name of Importer: Sadaat International. 2-Already Approved Same Antigen Product For E.Coli: Brand Name :(Nobilis E.Coli Inac) Pak Reg No. 017148 Pack Size: 500ml Name of Importer: Vety Care Private Ltd. Lahore.
	Stability data of finished product	The firm has submitted stability study data of 24-months conducted at 2°C to 8°C for three consecutive batches as below: • V05AM19OPN • V05AM19OPD • VO5AM19OPO
	Document Details	• Legalized FSC issued on March 31, 2022 issued by Ministry Of Agriculture, Directorate General Of Livestock And Animal Health Services. Indonesia. • Legalized Copy of GMP. • Legalized Copy of Manufacturing License. • Legalised Copy of Last Inspection Report.

		• Legalised Authorization Letter (SCANNED COPY).
	Remarks OF Evaluator: The application has been evaluated and shortcomings communicated a follows: • FSC does not contains the composition of the applied product. • Mention complete address of the manufacturing site at the label of subject product. • The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is reqd. • Provide the particular me too/generic status. • Pertinently, another firm importing the same class of products from same manufacturer but there is difference of 'live' and ;killed' vaccines.	
	Decision: **The registration board deferred the case for submission of following deficiencies;** • **Submission of FSC showing the composition of the applied product.** • **Revision of Label mentioning complete address of the manufacturing site at the label.** • **The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is reqd.** • **Provide the particular me too/generic status.**	
58	**Name of Importer**	M/sHuzaifa International, Commercial area, aziz bhatti town, Sargodha
	DSL details	DSL No.. . **08-384-0120-022405D**,valid till . 20 –11-2028.
	Name of Manufacturer	**Product License Holder & Manufacturer (As per : (CoPP** JILIN ZHENGYE BIOLOGICAL PRODUCTS CO.,LTD. : :AddressNo.1 Lian Meng Street Economic and technological Development Zone Of Jilin City, China
	+ Brand Name + Dosage Form Strength	POLY-VAC ND.IB.EDS Inactivated viral vaccine for the prevention of Newcastle disease, Infectious Bronchitis and Egg drop syndrome in poultry.
	Composition	Each dose contains: Contains the Inactivated Newcastle disease virus(Clone 30 strain),before Inactivated at least $3.0*10^{8.0}EID_{50}$/0.1ml; Chicken infectious bronchitis virus (M41 strain),before Inactivated at least $3.0*10^{6.0}EID_{50}$/0.1ml; Egg Drop Syndrome virus (AV127 strain),before Inactivated virus liquid HA at least 1:30720.
	Finished product specifications	Specifications ; European Pharmacopoeia specifications
	Pharmacological Group	Biological Product- Inactivated Veterinary vaccine
	Shelf life	12 Months)Store at 2~8°C)
	International availability	VAXXON ND-IB-EDS (In Netherlands)
	Products already registered in Pakistan	ITA ND.IB.EDS Vaccine; Registration holder; Vet line International, Lahore. Reg. no. 062005 (…….)
	Type of Form Dy. No. Date of Application, Fee submitted	.; Form5-ADy. No. Date:02-12-2022 .Fee Submitted: Rs 75,000, dated -/ : 11-11-2022
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 500 ml vaccine bottle
	General Documentation	• Original Legalized Free Sale certificate , GMP certificate and Authorization letter submitted

	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Kindly Submit the differential fee in the light of fee SRO.	
	<u>Decision: The registration board deferred the case for submission of following deficiencies;</u> • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- the differential fee in the light of fee SRO.	
59	**Name of Importer**	M/sHuzaifa International, Commercial area, aziz bhatti town, Sargodha
	DSL details	. ..DSL No08-384-0120-022405D,valid till . 20-11-2028
	Name of Manufacturer	**Product License Holder & Manufacturer (As per : (CoPP** JILIN ZHENGYE BIOLOGICAL PRODUCTS CO., LTD. : :AddressNo.1 Lian Meng Street Economic and technological Development Zone Of Jilin City, China
	+ Brand Name + Dosage Form Strength	POLY-VAC ND.IB.H9 Inactivated viral vaccine for the prevention of Newcastle disease, Infectious Bronchitis and Avian Influenza in poultry.
	Composition	Contains Newcastle disease virus LaSota strain (before inactivation the virus content≥$3*10^{8.0}EID_{50}$/0.1ml), Chicken infectious bronchitis virus M41strain（before inactivation the virus content≥$3*10^{6.0}EID_{50}$/0.1ml) and Avian influenza (H9N2 subtype) virus （before inactivation the virus content≥$3*10^{8.0}EID_{50}$/0.1ml）
	Finished product specifications	Specifications ; Innovator's specifications
	Pharmacological Group	Biological Product- Inactivated Veterinary vaccine
	Shelf life	12 Months)Store at 2~8°C)
	International availability	MEVAC Multi IB+H9+ND (In United kingdom)
	Products already registered in Pakistan	Pro-vac ABBN Vaccine; Registration holder; Huzaifa International, commercial area, aziz Bhatti town, Sargodha. Reg. no. 088167
	Type of Form Dy. No. Date of Application, Fee submitted	Form5-A Dy. No. Date:02-12-2022 .Fee Submitted: Rs 75,000, -/ dated: 11-11-2022
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 500 ml vaccine bottle
	General Documentation	• Original Legalized Free Sale certificate , GMP certificate and Authorization letter submitted
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per VICH guidlines. • Provide the label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider	

	for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- differential fee in the light of fee SRO.	
	Decision: The registration board deferred the case for submission of following deficiencies; • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- the differential fee in the light of fee SRO.	
60	**Name of Importer**	M/sHuzaifa International, Commercial area, aziz bhatti town, Sargodha
	DSL details	DSL No. **08-384-0120-022405D** Valid till 20-November – 2028
	Name of Manufacturer	Product License Holder & Manufacturer (As per CoPP :(,Komipharm International Co. Ltd. 17-Gyeongje-ro ..Siheung-Si, Gyeonggi-do, South Korea
	+ Brand Name + Dosage Form Strength	PRO-VAC Rabies-FC Inactivated rabies virus vaccine
	Composition	Each 1 ml contains: **:Active substance** Rabies-Fc antigen (Pasteur strain) ..... $10^{7.0}FAID_{50}$*
	Finished product specifications	Specifications ; European Pharmacopoeia specifications
	Pharmacological Group	Biological Product- Veterinary vaccine
	Shelf life	Months (At 2-8 ℃) 36
	International availability	Rabicin Vaccine, Boeringer Ingelheim GmbH, Germany
	Products already registered in Pakistan	Saadat International ,Lahore, Rabicin vaccine, Reg. No. 006853
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-AA Dy. No. 14-07-2022 .Fee Submitted: Rs 75,000 -/ dated: 22-06-2022
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 1 ml (1 Dose) vaccine
	General Documentation	• Original Legalized Free Sale certificate , GMP certificate and Authorization letter
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per VICH guidlines. • Provide the label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Kindly Submit the differential fee in the light of fee SRO.	
	Decision: The registration board deferred the case for submission of following deficiencies; • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- the differential fee in the light of fee SRO.	

61	**Name of Importer**	**M/s Hipra Pakistan (Private) Limited, House no 86-88, J-1, Sunflower Society, Johar Town, Lahore**
	DSL details	License to sell drug as distributor No. 05-352-0058-050528D valid till 19-Feb-2029
	Name of Manufacturer	**Laboratorios HIPRA, S.A, Avda. La Selva, 135 17170 Amer (Girona) Spain**
	Brand Name + Dosage Form + Strength	HIPRADOG-DP, 1 dose *10, powder and solvent for injectable suspension
	Composition	Composition per 1ml dose: **Freez dried fraction:** Attenuated Canine Parvovirus, strain C-780916 ..... $\geq 10^7$ $DICT_{50}$ **Liquid Fraction:** Attenuated Canine Distemper Virus, strain Lederle ... $\geq 10^5$ $DICT_{50}$
	Finished product specifications	Innovators specifications
	Pharmacological Group	Live vaccine against canine parvovirosis and canine distemper.
	Shelf life	18 Months (Store at 2 – 8°C.)
	International availability	Spain
	Products already registered in Pakistan	HIPRADOG-7
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dated: 16-01-2023 Fee Submitted: Rs. 150,,000 /- dated
	Demanded Price / Pack size	1dose* 10 Decontrollered for Veterinary products
	General Documentation	• Legalized Certificate of Pharmaceutical Product (CoPP) No.....issued by Agencia Espanola de Medicamentos y productos sanitarios dated: valid for ..... (if written)
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows • FSC does not matched the composition of applied product in form-5A, So submit revised form-5A. • Submit the Original and notarized LoA with clarified statement of agreement and validity. • Clinical Safety data and product stability Data should be submitted in line with ICH guidlines. • Clarity is required that the product is a live vaccine or in otherwise? Clearly mention the mode of latency and genicity of the subject viral vaccine. • Submit the sufficient and fresh quality control data that assures safety of the product [Viral Load and its dose determination needs to be explained].	
	Decision: The registration board deferred the case for submission of following; • FSC does not matched the composition of applied product in form-5A, so submit revised form-5A. • Submit the Original and notarized LoA with clarified statement of agreement and validity. • Clinical Safety data and product stability Data should be submitted in line with ICH guidelines. • Clarity is required that the product is a live vaccine or in otherwise? Clearly mention the mode of latency and genicity of the subject viral vaccine. • Submit the sufficient and fresh quality control data that assures safety of the product [Viral Load and its dose determination needs to be explained].	
62	**Name of Importer**	**M/s Hipra Pakistan (Private) Limited, House no 86-88, J-1, Sunflower Society, Johar Town, Lahore**
	DSL details	License to sell drug as distributor No. 05-352-0058-050528D valid till 19-Feb-2029
	Name of	**Laboratorios HIPRA, S.A,**

	Manufacturer	**Avda. La Selva, 135, 17170 Amer (Girona) Spain**
	Brand Name + Dosage Form + Strength	HIPRADOG-PV, 10 doses, injectable suspension
	Composition	Strength per dose (1 ml): Canine Parvovirus, Attenuated strain C-780916 ..... $\geq 10^7$ $TCID_{50}$
	Finished product specifications	Innovators specifications
	Pharmacological Group	Live vaccine against canine parvovirosis
	Shelf life	18 Months (Store at 2 – 8°C.)
	International availability	Spain
	Products already registered in Pakistan	HIPRADOG-7
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dated: 16-01-2023 Fee Submitted: Rs. 150,,000 /- dated
	Demanded Price / Pack size	10 doses Decontrollered for Veterinary products
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows • FSC does not matched the composition of applied product in form-5A, So submit revised form-5A. • Submit the Original and notarized LoA with clarified statement of agreement and validity. • Clinical Safety data and product stability Data should be submitted in line with ICH guidlines. • Clarity is required that the product is a live vaccine or in otherwise? Clearly mention the mode of latency and genicity of the subject viral vaccine. • Submit the sufficient and fresh quality control data that assures safety of the product [Viral Load and its dose determination needs to be explained].	
	Decision: The registration board deferred the case for submission of following deficiencies; • FSC does not matched the composition of applied product in form-5A, so submit revised form-5A. • Submit the Original and notarized LoA with clarified statement of agreement and validity. • Clinical Safety data and product stability Data should be submitted in line with V-ICH guidelines. • Clarity is required that the product is a live vaccine or in otherwise? Clearly mention the mode of latency and genicity of the subject viral vaccine. • Submit the sufficient and fresh quality control data that assures safety of the product [Viral Load and its dose determination needs to be explained].	

63	Name of Importer	**Hilton Pharma (Pvt.) Ltd. Plot 13-14 & 43, Sector 15, Korangi Industrial Area Karachi.**
	DSL details	License to sell drug as distributor. License No. 550, valid till 19-Jun-2024
	Name of Manufacturer	**Jaya M/s PT. Medion Farma** Office Address: JI. Babakan Ciparay No. 282, Babakan Ciparay, Bandung-Indonesia Plant Address: JI. Raya Batujajar No. 29, Cimareme, Ngamprah , Bandung Barat-Indonesia
	Brand Name+ Dosage Form+ Strength	MEDIVAC GUMBOPLEX VACCINE 2000 DOSES (Freeze dried immune complex vaccine for poultry)
	Composition	Each dose contains: Infectious Bursal Disease (IBD) /Gumboro disease virus of Winterfield 2512 strain combined with specific hyperimmune serum of IBD…… at least $10^{2.0}$ EID_{50} IBD Virus.

	Finished product specifications	Innovator's Specification
	Pharmacological Group	Freeze dried immune complex vaccine against infectious Bursal disease (IBD) in poultry
	Shelf life	24 Months (2-8°C)
	Products already registered in Pakistan	Bursaplex Vaccine (Reg No. 020775) by U.M Enterprises Karachi
	Type of Form; Dy. No. Date of Application, Fee submitted	Form 5-A Dy No. Dated: 29-Dec-2022; Fee Submitted: Rs. 150,000/- (Fee deposited challan no. 1982978732), dated 14-12-2022
	Demanded Price / Pack size	2000 Doses
	General Documentation	Firm has submitted • Legalized GMP Certificate No. 193-GMP-2021 dated 8th September 2021 issued by Ministry of Agriculture Directorate General of livestock and animal health services Indonesia. (Valid till 8th September 2026) • Legalized Certificate of Pharmaceutical Product (CoPP) No 27042/PI.500/F/04/2022 dated April 17,2022 issued by Ministry of Agriculture Directorate General of livestock and animal health services Indonesia.
	Stability Study	Firm has submitted the stability data. Medivac Gumboplex complies with the specifications, for 27 months if its stability studies stored at 2-8 °C. Batch No. 98J107, 98J108, 98J109
	Me too/Generic Status	UM Enterprises Bursaplex IBD Virus, Strain 2512 100 EID_{50} / Dose at release Bursal Disease antiserum 24U per dose Gentacin 30mg/L 020775 Firm has submitted evidence of local availability of Bursaplex approved in 254th RB.
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: - • FSC does not matched the composition of applied product in form-5A, so submit revised form-5A. • Details of Clinical studies and CoA not provided.	
Decision: The registration board approved the case subject to submission of following; • Details of Clinical (Safety & Efficacy) data should be submitted in line with V-ICH guidelines and Submit the fresh CoAs.		
64	Name of Importer	Hilton Pharma (Pvt.) Ltd. Plot 13-14 & 43, Sector 15, Korangi Industrial Area Karachi.
	DSL details	License to sell drug as distributor. License No. 550, valid till 19-Jun-2024
	Name of Manufacturer	**Jaya M/s PT. Medion Farma** Office Address: JI. Babakan Ciparay No. 282, Babakan Ciparay, Bandung-Indonesia Plant Address: JI. Raya Batujajar No. 29, Cimareme, Ngamprah , Bandung Barat-Indonesia
	Brand Name+ Dosage Form+ Strength	MEDIVAC GUMBOPLEX VACCINE 1000 DOSES (Freeze dried immune complex vaccine for poultry)
	Composition	Active ingrediand amount per unit dose: Infectious Bursal Disease (IBD) /Gumboro disease virus of Winterfield 2512 strain combined with specific hyperimmune serum of IBD…… at least $10^{2.0}$ EID_{50} IBD Virus.

	Finished product specifications	Innovator's Specification
	Pharmacological Group	Freeze dried immune complex vaccine against infectious Bursal disease (IBD) in poultry
	Shelf life	24 Months (2-8°C)
	Products already registered in Pakistan	Bursaplex Vaccine (Reg no. 020775) by U.M Enterprises Karachi
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy No.39330 Dated: 29-Dec-2022 Fee Submitted: Rs. 150,000/- (Challan # 2431302874) dated 08-12-2022
	Demanded Price / Pack size	1000 Doses
	General Documentation	Firm has submitted • Legalized GMP Certificate No. 193-GMP-2021 dated 8th September 2021 issued by Ministry of Agriculture Directorate General of livestock and animal health services Indonesia. (Valid till 8th September 2026) • Legalized Certificate of Pharmaceutical Product (CoPP) No 27042/PI.500/F/04/2022 dated April 17,2022 issued by Ministry of Agriculture Directorate General of livestock and animal health services Indonesia.
	Stability Study	Firm has submitted the stability data. Medivac Gumboplex complies with the specifications, for 27 months if its stability studies stored at 2-8 °C. Batch No. 98J107, 98J108, 98J109
	Me too/ Generic status	Firm has submitted evidence of local availability of Bursaplex approved in 254 DRB. UM Enterprises Bursaplex IBD Virus, Strain 2512 100 EID_{50} / Dose at release Bursal Disease antiserum 24U per dose Gentacin 30mg/L 020775
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: - • FSC does not matched the composition of applied product in form-5A, so submit revised form-5A. • Details of Clinical studies and CoA not provided.	
Decision: The registration board approved the case subject to submission of following; • Details of Clinical (Safety & Efficacy) data should be submitted in line with V-ICH guidelines and Submit the fresh CoAs.		

- **WITHDRAWAL OF REGISTRATION APPLICATIONS OF BIOLOGICAL DRUGS.**

The following importing firms are withdrawing their registration applications of medical devices as mentioned against each. The firms have also not deposited differential fee as per revised fee schedule for their products: -

Sr.#.	Name of Importer	Manufacture/Exporter or MAH.	Name of Drug(s)
66	M/s. Vety-Care Pvt. Ltd., I-10/3, Industrial Estate Islamabad.	M/s. Intervet International B. V Wim De Korverstraat 35, Boxemeer Netherland.	NOBILIS MS LIVE
67	-do-	M/s. Laboratories Calier SA. Pol. Ind. Deleon Ed. CEEI-Onzonilla (Leon_-24231 Spain.	NOBILIS SE LIVE
68	Saadat	M/s. Boehringer Ingelheim Animal Health S.Pa., Italia.	GALLIMUNE H9 + ND + IBD

	International 117-Habitat Apartments, Shadman-II, Jail Road, Lahore.		
69	-do-	-do-	GALLIMUNE REO
70	-do-	-do-	GALLIMUNE 201 IBD+REO
71	-do-	-do-	GALLIMUNE ART
72	-do-	-do-	GALLIMUNE MG
73	-do-	-do-	GALLIMUNE 403 ND + IB+ IBD+REO
WITHDRAWAL OF ALREADY REGISTERED PRODUCTS.			
74	Saadat International 117-Habitat Apartments, Shadman-II, Jail Road, Lahore.	M/s. Boehringer Ingelheim Animal Health S.Pa., Italia.	ANGAVAC. Regn.#. 019924
75	-do-	-do-	Gallimune Cholera. Regn. # 034557
76	-do-	-do-	GALLIMUNE 503 ND + IB+ EDS+IC2. Regn. # 034558.
77	-do-	-do-	BDA Blen 1000ds Regn. # 082025.
78	-do-	-do-	LT Blen. Regn. # 082027.

Decision: The Registration Board acceded the request for withdrawal of abovementioned products.

CASES OF DD-III (MS. HALEEMA SHARIF)

Imported Human Biologicals from non-reference countries:

79.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt).Ltd, Lahore < Pakistan**
	Details of the Drug Sale License of the importer	**License No: 5-352-0066-059010D** **Address:** BF1-01 First Floor Gate No.1 Bahria Orchard Main Raiwind Road Distt Lahore **Address of Godown:** 247-Sundar Industrial Estate, Lahore **Validity: 27.08.2027** **Status:** License to sell drugs as a distributor **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea
	Name, and address of the manufacturer(s)	M/s. Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Name of the exporting country	Korea

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized CoPP certificate (No.2022-AI-0749) dated 02.05.2022 issued by ministry of food and drug safety for Nesbell PFS . The CoPP confirms the free sale status of the product in exporting country as well as the GMP status of the manufacturing site through periodic inspection every three years.
	Details of letter of authorization / sole agency agreement	The firm has submitted a distribution supply agreement from Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	Status of application	☒ **New Drug Product (NDP)** ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4945_dated__21 Feb 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Nesbell Prefilled Syringe™ 20 ug**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5 ml PFS contains Darbepoetin alfa…….20ug (Recombinant protein
	Pharmaceutical form of applied drug	Clear Colorless solution for injection filled in prefilled glass syringe with a single use needle
	Pharmacotherapeutic Group of (API)	erythropoiesis-stimulating agents (ESAs)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Aranesp® (USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Name, address of drug substance manufacturer	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass Syringe and rubber closure made of bromo butyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at (25℃±2℃/60%RH±5%RH for 6 months. The real time stability study data is conducted at (5℃±3℃,) The real time stability study data of 3 batches is for 24 months.
	Module IV	Following studies have been performed by the firm • Single dose toxicity studies. • Repeat dose toxicity studies.
	Module V	Randomized, double-blind, multi-center and phase 3 clinical trial to evaluate the efficacy and safety of CKD-11101 or Darbepoetin alfa administered subcutaneously for treatment of anemia in patients with chronic renal failure not receiving dialysis. A Randomized, Double-blind, Multi-center, Phase III Trial toEvaluate the Efficacy and Safety

		of CKD-11101 or Darbepoetin alfa Administered Intravenously for Treatment of Anemia in Patients with Chronic Renal Failure Receiving Hemodialysis

Evaluation by PEC:

- Evidence of approval of applied formulation Darbepoetin alfa 20ug/0.5ml PFS in reference agencies adopted by Registration Board is required.
- On CoPP it is mentioned that for complete quantitative composition including excipients, see attached but there is not attachment with CoPP.
- According to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is " Binex Co., Ltd" but distribution agreement is with "M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea"

** We, Chong Kun Dang Pharmaceutical Corp (hereinafter CKD), hereby declare that we are the actual manufacturer and market authorization holder of the finished biosimilar product, Nesbell Prefilled Syringe (20,30,40,60,120mcg).
There have been two manufacture ring facilities listed in the MFDS (Ministry of Food and Drug Safety) product license. One is CKD and the other is Binex.
In fact, according to the MFDS CPP issuing practice, Section 2.4 Status of product-license holder of the CPP only one option can be selected and this can be shown as Binex as the only manufacturer which is not true. Due to the inconvenience of the electronic document issuance form with no choice given from our MFDS system, here we explain in precise detail to avoid any misunderstanding. Therefore, we have added attachment on page 4, representing the full tabular list of all manufacturers.
Although Nesbell Prefilled syringe is no longer produced from Binex facility, we are obliged to keep all records of previous manufacturers information Despite the fact that CMO business contract between CKD (Consigner) and Binex (Consignee) had terminated, the quality agreement of the previously manufactured and domestically distributed products are still valid.

- Firm has submitted fee of Rupee 75000/- only considering it a new drug application.

Decision:
Registration Board deferred the case for following:

- **Original notrised CoPP indicating Quantitative composition of applied formulation including excipients.**
- **Clarification regarding product license holder, Manufacturer is required as according to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" But in declaration letter it is mentioned that CKD is actual manufacturer and Bionex is no longer manufacturer.**
- **Distribution agreement is with M/s. Medicalcine Inc, Korea not with CKD provide details of working link between CKD and Medicalcine Inc. OR Distribution agreement with M/s. CKD.**
- **Evidence of approval of Darbepoetin alfa 20ug/0.5ml PFS in reference agencies adopted by Registration Board.**

80.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt).Ltd, Lahore < Pakistan**
	Details of the Drug Sale License of the importer	**License No: 5-352-0066-059010D** **Address:** BF1-01 First Floor Gate No.1 Bahria Orchard Main Raiwind Road Distt Lahore **Address of Godown:** 247-Sundar Industrial Estate, Lahore **Validity: 27.08.2027** **Status:** License to sell drugs as a distributor **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea

	Name, and address of the manufacturer(s)	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Name of the exporting country	Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized CoPP certificate (No.2022-AI-0749) dated 02.05.2022 issued by ministry of food and drug safety for Nesbell PFS . The CoPP confirms the free sale status of the product in exporting country as well as the GMP status of the manufacturing site through periodic inspection every three years.
	Details of letter of authorization / sole agency agreement	The firm has submitted a distribution supply agreement from Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	Status of application	☒ **New Drug Product (NDP)** ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.4947 dated 21 Feb 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Nesbell Prefilled Syringe™ 30 ug**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5 ml PFS contains Darbepoetin alfa…….30 ug (Recombinant protein
	Pharmaceutical form of applied drug	Clear Colorless solution for injection filled in prefilled glass syringe with a single use needle
	Pharmacotherapeutic Group of (API)	erythropoiesis-stimulating agents (ESAs)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Aranesp® (USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass Syringe and rubber closure made of bromo butyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at (25℃±2℃/60%RH±5%RH for 6 months. The real time stability study data is conducted at (5℃±3℃,) The real time stability study data of 3 batches is for 24 months.
	Module IV	Following studies have been performed by the firm • Single dose toxicity studies. • Repeat dose toxicity studies.

	Module V	Randomized, double-blind, multi-center and phase 3 clinical trial to evaluate the efficacy and safety of CKD-11101 or Darbepoetin alfa administered subcutaneously for treatment of anemia in patients with chronic renal failure not receiving dialysis. A Randomized, Double-blind, Multi-center, Phase III Trial toEvaluate the Efficacy and Safety of CKD-11101 or Darbepoetin alfa Administered Intravenously for Treatment of Anemia in Patients with Chronic Renal Failure Receiving Hemodialysis

Evaluation by PEC:

- Evidence of approval applied formulation with applied volume (0.5ml) in reference agency is required.
- On CoPP it is mentioned that for complete quantitative composition including excipients, see attached but there is not attachment with CoPP.
- According to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" but distribution agreement is with "M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea"
- Firm has submitted fee of Rupee 75000/- only considering it a new drug application.

Decision:

Registration Board deferred the case for following:

- **Original notrised CoPP indicating Quantitative composition of applied formulation including excipients.**
- **Clarification regarding product license holder, Manufacturer is required as according to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" But in declaration letter it is mentioned that CKD is actual manufacturer and Bionex is no longer manufacturer.**
- **Distribution agreement is with M/s. Medicalcine Inc, Korea not with CKD provide details of working link between CKD and Medicalcine Inc. OR Distribution agreement with M/s. CKD.**
- **Evidence of approval of Darbepoetin alfa 30ug/0.5ml PFS in reference agencies adopted by Registration Board.**

81.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt).Ltd, Lahore < Pakistan**
	Details of the Drug Sale License of the importer	**License No: 5-352-0066-059010D** **Address:** BF1-01 First Floor Gate No.1 Bahria Orchard Main Raiwind Road Distt Lahore **Address of Godown:** 247-Sundar Industrial Estate, Lahore **Validity: 27.08.2027** **Status:** License to sell drugs as a distributor **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea
	Name, and address of the manufacturer(s)	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Name of the exporting country	Korea

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized CoPP certificate (No.2022-AI-0749) dated 02.05.2022 issued by ministry of food and drug safety for Nesbell PFS . The CoPP confirms the free sale status of the product in exporting country as well as the GMP status of the manufacturing site through periodic inspection every three years.
	Details of letter of authorization / sole agency agreement	The firm has submitted a distribution supply agreement from Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	Status of application	☒ **New Drug Product (NDP)** ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4946 dated_21 Feb 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Nesbell Prefilled Syringe™ 40 ug**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5 ml PFS contains Darbepoetin alfa…….40ug (Recombinant protein
	Pharmaceutical form of applied drug	Clear Colorless solution for injection filled in prefilled glass syringe with a single use needle
	Pharmacotherapeutic Group of (API)	erythropoiesis-stimulating agents (ESAs)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC_____
	The status in reference regulatory authorities	**Aranesp® (USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Name, address of drug substance manufacturer	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20ºC ± 5ºC. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass Syringe and rubber closure made of bromo butyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at (25℃±2℃/60%RH±5%RH for 6 months. The real time stability study data is conducted at (5℃±3℃,) The real time stability study data of 3 batches is for 24 months .
	Module IV	Following studies have been performed by the firm • Single dose toxicity studies. • Repeat dose toxicity studies.
	Module V	Randomized, double-blind, multi-center and phase 3 clinical trial to evaluate the efficacy and safety of CKD-11101 or Darbepoetin alfa administered subcutaneously for treatment of anemia in patients with chronic renal failure not receiving dialysis.

		A Randomized, Double-blind, Multi-center, Phase III Trial toEvaluate the Efficacy and Safety of CKD-11101 or Darbepoetin alfa Administered Intravenously for Treatment of Anemia in Patients with Chronic Renal Failure Receiving Hemodialysis

Evaluation by PEC:

- Evidence of approval applied formulation with applied volume (0.5ml) in reference agency is required.
- On CoPP it is mentioned that for complete quantitative composition including excipients, see attached but there is not attachment with CoPP.
- According to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is " Binex Co., Ltd" but distribution agreement is with "M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea"
- Firm has submitted fee of Rupee 75000/- only considering it a new drug application.

Decision:

Registration Board deferred the case for following:

- **Original notrised CoPP indicating Quantitative composition of applied formulation including excipients.**
- **Clarification regarding product license holder, Manufacturer is required as according to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" But in declaration letter it is mentioned that CKD is actual manufacturer and Bionex is no longer manufacturer.**
- **Distribution agreement is with M/s. Medicalcine Inc, Korea not with M/s. CKD provide details of working link between CKD and Medicalcine Inc. OR Distribution agreement with M/s. CKD.**
- **Evidence of approval of Darbepoetin alfa 40ug/0.5ml PFS in reference agencies adopted by Registration Board.**

82.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt).Ltd, Lahore < Pakistan**
	Details of the Drug Sale License of the importer	**License No: 5-352-0066-059010D** **Address:** BF1-01 First Floor Gate No.1 Bahria Orchard Main Raiwind Road Distt Lahore **Address of Godown:** 247-Sundar Industrial Estate, Lahore **Validity: 27.08.2027** **Status:** License to sell drugs as a distributor **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea
	Name, and address of the manufacturer(s)	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Name of the exporting country	Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized **copy** of the CoPP certificate (No.2022-AI-0749) dated 02.05.2022 issued by ministry of food and drug safety for Nesbell PFS . The CoPP confirms the free sale status of the product in exporting country as well as the GMP status of the manufacturing site through periodic inspection every three years.

	Details of letter of authorization / sole agency agreement	The firm has submitted a distribution supply agreement from Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	Status of application	☒ **New Drug Product (NDP)** ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4944 dated 21 Feb 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Nesbell Prefilled Syringe™ 60 ug**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5 ml PFS contains Darbepoetin alfa…….60ug (Recombinant protein
	Pharmaceutical form of applied drug	Clear Colorless solution for injection filled in prefilled glass syringe with a single use needle
	Pharmacotherapeutic Group of (API)	erythropoiesis-stimulating agents (ESAs)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC_____
	The status in reference regulatory authorities	**Aranesp® (USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20ºC ± 5ºC. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass Syringe and rubber closure made of bromo butyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at (25℃±2℃/60%RH±5%RH for 6 months. The real time stability study data is conducted at (5℃±3℃,) The real time stability study data of 3 batches is for 24 months .
	Module IV	Following studies have been performed by the firm • Single dose toxicity studies. • Repeat dose toxicity studies.
	Module V	Randomized, double-blind, multi-center and phase 3 clinical trial to evaluate the efficacy and safety of CKD-11101 or Darbepoetin alfa administered subcutaneously for treatment of anemia in patients with chronic renal failure not receiving dialysis. A Randomized, Double-blind, Multi-center, Phase III Trial toEvaluate the Efficacy and Safety of CKD-11101 or Darbepoetin alfa Administered Intravenously for Treatment of Anemia in Patients with Chronic Renal Failure Receiving Hemodialysis
Evaluation by PEC: • Evidence of approval applied formulation with applied volume (0.5ml) in reference agency is required.		

- On CoPP it is mentioned that for complete quantitative composition including excipients, see attached but there is not attachment with CoPP.
- According to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is " Binex Co., Ltd" but distribution agreement is with "M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea"
- Firm has submitted fee of Rupee 75000/- only considering it a new drug application.

Decision:
Registration Board deferred the case for following:

- **Original notrised CoPP indicating Quantitative composition of applied formulation including excipients.**
- **Clarification regarding product license holder, Manufacturer is required as according to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" But in declaration letter it is mentioned that CKD is actual manufacturer and Bionex is no longer manufacturer.**
- **Distribution agreement is with M/s. Medicalcine Inc, Korea not with CKD provide details of working link between CKD and Medicalcine Inc. OR Distribution agreement with M/s. CKD.**
- **Evidence of approval of Darbepoetin alfa 60ug/0.5ml PFS in reference agencies adopted by Registration Board.**

83.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt).Ltd, Lahore < Pakistan**
	Details of the Drug Sale License of the importer	**License No: 5-352-0066-059010D** **Address:** BF1-01 First Floor Gate No.1 Bahria Orchard Main Raiwind Road Distt Lahore **Address of Godown:** 247-Sundar Industrial Estate, Lahore **Validity: 27.08.2027** **Status:** License to sell drugs as a distributor **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea
	Name, and address of the manufacturer(s)	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Name of the exporting country	Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized **copy** of the CoPP certificate (No.2022-AI-0749) dated 02.05.2022 issued by ministry of food and drug safety for Nesbell PFS . The CoPP confirms the free sale status of the product in exporting country as well as the GMP status of the manufacturing site through periodic inspection every three years.
	Details of letter of authorization / sole agency agreement	The firm has submitted a distribution supply agreement from Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract

		giver)
	Status of application	☒ **New Drug Product (NDP)** ☐ Generic Drug Product (GDP**)**
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.4948 21 Feb 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Nesbell Prefilled Syringe™ 120 ug**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5 ml PFS contains Darbepoetin alfa…….120ug (Recombinant protein
	Pharmaceutical form of applied drug	Clear Colorless solution for injection filled in prefilled glass syringe with a single use needle
	Pharmacotherapeutic Group of (API)	erythropoiesis-stimulating agents (ESAs)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC_____
	The status in reference regulatory authorities	**Aranesp® (USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Chong Kun Dang Pharmaceutical Corporation located at 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea of Republic
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3

	(Conditions & duration of Stability studies)	batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20ºC ± 5ºC. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass Syringe and rubber closure made of bromo butyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at (25℃±2℃/60%RH±5%RH for 6 months. The real time stability study data is conducted at (5℃±3℃,) The real time stability study data of 3 batches is for 24 months.
	Module IV	Following studies have been performed by the firm • Single dose toxicity studies. • Repeat dose toxicity studies.
	Module V	Randomized, double-blind, multi-center and phase 3 clinical trial to evaluate the efficacy and safety of CKD-11101 or Darbepoetin alfa administered subcutaneously for treatment of anemia in patients with chronic renal failure not receiving dialysis. A Randomized, Double-blind, Multi-center, Phase III Trial toEvaluate the Efficacy and Safety of CKD-11101 or Darbepoetin alfa Administered Intravenously for Treatment of Anemia in Patients with Chronic Renal Failure Receiving Hemodialysis

Evaluation by PEC:

- Evidence of approval applied formulation with applied volume (0.5ml) in reference agency is required.
- On CoPP it is mentioned that for complete quantitative composition including excipients, see attached but there is not attachment with CoPP.
- According to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is " Binex Co., Ltd" but distribution agreement is with "M/s. Medicalcine Inc, located at 1109 22, Hyoryeong-ro 55-gil, Seocho-gu, Seoul 06654 Korea"
- Firm has submitted fee of Rupee 75000/- only considering it a new drug application.

Decision:
Registration Board deferred the case for following:

• **Original notrised CoPP indicating Quantitative composition of applied formulation including excipients.** • **Clarification regarding product license holder, Manufacturer is required as according to CoPP product license holder is "M/s. Chong Kun Dang Pharmaceutical Corporation" and manufacturer is "Binex Co., Ltd" But in declaration letter it is mentioned that CKD is actual manufacturer and Bionex is no longer manufacturer.** • **Distribution agreement is with M/s. Medicalcine Inc, Korea not with CKD provide details of of working link between CKD and Medicalcine Inc. OR Dustribution agreement with M/s. CKD.** • **Evidence of approval of Darbepoetin alfa 120ug/0.5ml PFS in reference agencies adopted by Registration Board.**		
84.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt) Ltd., Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0065-016174D **Validity**: 06-02-2024 **Address of Godown:** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan Lahore. **Status**: License to sell drugs as a distributor. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited., Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited., Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (DA/6-110/2016/13527) dated 19-07-2023 issued by Ministry of Health & Family welfare, Directorate General of Drug Administration, Dhaka. The CoPP confirms free sale status of the product in exporting country as well as GMP status as recommended by the World Health Organization.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Beacon Pharmaceuticals limited. The letter specifies that Himmel Pharmaceuticals (Pvt) Ltd., Pakistan is an authorized agent of Beacon Pharmaceuticals Limited to register and sell the product in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging

		☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	(R&I) Dated 00-00-2023
	Details of fee submitted	Rs. 150,000/- Dated 15-08-2023
	The proposed proprietary name / brand name	Eptase Injection 15,00,000 IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Streptokinase BP…..…15,00,000 Units
	Dosage form of applied drug	Lyophilized powder for Injection
	Pharmacotherapeutic Group of (API)	Fibrinolytic agent
	Finished product specifications	BP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO/DPC
	Shelf life	24 months
	Storage conditions	2 - 8 °C.
	The status in reference regulatory authorities	Icikinase of Abbott, USA Streptase of CSL Behring, Germany
	For generic drugs (me-too status)	Diclair-ST of Gene-Tech pharma
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Levim Biotech LLP, Ticel Biopark Ltd., Phase –II, 501-505, CSIR Road , Taramani Chennai.
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of following 3 batches of drug substance conducted at 5 ± 3°C for 24 months: RSKFB16001 RSKFB16003 RSKFB16005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Glass vials • Rubber stopper • Flip off seal
	Stability study data of drug product	Firm has submitted stability study data of 3 batches is conducted at 2 °C to 8 °C for 24 months. 1030001 1030002 1030003
	Non-clinical (Module-IV)	The firm has submitted following: "*The active material of Eptase Injection is Streptokinase which is a Generic product and a well-established existing substance or molecule. Pharmacology, Pharmacokinetics and toxicology profile of Finished Products is pre-set and well defined. That is why this part of the module is not necessary*."
	Clinical (Module-V)	Not applicable.
	Remarks of evaluator	• The submitted copy of DSL was valid till 06.02.2024. • The firm has submitted copy of sole agency agreement. • The firm has not submitted clinical and non-clinical studies for applied product. • The firm has not submitted Bio similarity data as per WHO guidelines.
Decision: Registration Board deferred the case for submission of the following: **i. Valid copy of DSL** **ii. Original or notarized copy of sole agency agreement.** **iii. Module IV (safety studies) Module V (Efficacy studies)/Bio similarity data as per WHO guidelines.**		

Imported Veterinary Biologicals from Non-Reference Countries:

85.	**Name and address of Importer**	**M/s. Jovac Global-PAK,** Plot No. 17, Block D, EME, DHA Phase 12, Lahore
	Detail of DSL	M/s. Jovac Global-PAK Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore. Valid up to:15.06.2023
	Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Name of exporting country	Jordan
	Brand Name +Dosage Form + Strength	**Jova Zeit H5N8 vaccine, Injectable water in oil emulsion**
	Diary No. Date of R& I & fee	Dy. No. 503 R&I Dated 31-01-2024 Rs. 150,000/- (Slip No. 3016579226)
	Composition	Each 0.25ml of vaccine contains: At least 10^8 EID_{50} inactivated Avian Influenza subtype H5N8.
	Pharmacological Group	Vaccine
	Type of Form	Form-5A

	Finished Product Specification	Manufacturer's specifications
	Shelf Life	2 years (store below 2-8^{0}C)
	Document Details	a. Valid legalized free sale certificate is submitted by the firm. b. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020. c. Firm has submitted notarized distribution agreement & Authorization letter
	Pack size	500ml bottle
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Otto FLU Plus Vac of Ottoman Pharma. Inactivated Avian Influenza H5 Virus Oil based vaccine.
	Remarks of Evaluator	Firm has submitted safety studies on 120 Birds and efficacy studies on 20 Birds.
	Decision: Registration Board deferred the case for submission of Field Trial Data OR Efficacy studies on larger number of Birds.	

Deferred cases/miscellaneous cases

86.	**Name and address of Importer**	**M/s Chakwal Pharma International,** O.T.I Plaza, Basement Ground, 1st,2nd & 3rd Floor 210-Lalazar Commercial Market, Thokar Naiz Baig, Raiwind Road. Lahore
	Detail of DSL	**M/s Chakwal Pharma International,** Address: O.T.I Plaza, Basement Ground, 1st,2nd & 3rd Floor 210-Lalazar Commercial Market, Thokar Naiz Baig, Raiwind Road. Lahore Valid till:
	Name and address of Manufacturer	**Manufacturer of Drug:** M/s Kyoto Biken Laboratories, Inc. 24-16, Makishima-Cho, Uji-Shi-Kyoto-fu, Japan
	Name of exporting country	Japan
	Brand Name +Dosage Form + Strength	"Kyoto Biken" Cattlewin -5K(Inactivated)
	Diary No. Date of R& I & fee	Dy. No. 5196 R&I Dated 03-05-2019 Fee challan of Rs. 50,000/- (deposit slip No. 07658493298 dated: 24/4/2019) Fee challan of Rs. 50,000/- (deposit slip No. 990498960)
	Composition	Each vial of 20ml contains: Infectious bovine rhinotracheitis virus, strain N., 758-Kb cultured in MDBK-NSC cells …..$10^{8.5}$ $TCID_{50}$ or more (before inactivation). Bovine viral diarrhea virus type 1, strain Nose-KB cultured in MDBK-NSc Cells(seed)….$10^{8.1}$ $TCID_{50}$ or more (before inactivation). Bovine viral diarrhea virus, type 2, strain KZ-91-KB cultured in MDBK-NSc Cells(seed) ….$10^{6.9}$ $TCID_{50}$ or more (before inactivation). Bovine parainfluenza virus, type 3, strain BN_1-1-KB cultured on MDBK-NSc Cells(seed) …$10^{8.4}$ $TCID_{50}$ or more (before inactivation). Bovine respiratory syncytial virus, strain rs-52 cultured in HmLu-SC cells (seed)…. $10^{7.1}$ $TCID_{50}$ or more (before inactivation).
	Pharmacological Group	Biological
	Type of Form	Form-5A

Finished Product Specification	As per innovator's Specifications
Shelf Life	30months----(2-10^{o}C)
Document Details	**COPP (Original Legalized):** Issued to: M/s Kyoto Biken Laboratories, Inc. 24-16, Makishima-Cho, Uji-Shi-Kyoto-fu, Japan (Manufacturer). Issued by: Animal Product Safety Division Food safety and Consumer Affairs Bureau, Ministry of Agriculture Forestry and Fisheries. Issued on: January 16, 2019. **Sole Agency Agreement:** Between M/s Kyoto Biken Laboratories, Inc. and M/s Chakwal Pharma International valid for five years from date of signing i.e. 11th September 2018.
Pack size	1's: 20ml vial
Reference Regulatory Authority Availability	Allowed to be sold in Japan as per COPP.
Products already registered in Pakistan	Strains of viruses are different. **Reg No. 094780, HIPRABOVIS-4 of "HIPRA Pakistan Pvt Ltd Lahore"** Lyophilisate and solvent for Injectable suspension Composition per dose (3ml): Composition of Liquid fraction: Inactivated Infectious Bovine Rinotracheitis Virus, strain LA……..…ELISA≥50 Inactivated Parainfluenza-3 virus, strain SF4…….…….IHA≥1/16 Inactivated Bovine Viral Diarrhoea Virus, strain NADL……ELISA≥50 Composition of freeze-dried fraction: Live Bovine Respiratory Syncytial Virus, strain Lym-56……...≥104TCID *ELISA: Antibody titre determined by ELISA in vaccinated rabbits. **IHA: Antibody titre determined by hemagglutination inhibition in vaccinated rabbits. ***CCID50: Cellular culture infective dose 50%
Remarks of Evaluator	Firm has submitted following: a. Fee challan differential fee of Rs. 50,000/- (deposit slip No. 990498960) b. Finished Product Specifications: As per innovator's specification. c. Stability studies data of three batches. d. Pack size: 20ml vial. e. For only brand name on COPP (as COPP does not mention composition and pack size). The firm submitted that original legalized FSC is certified by Director General of food security and consumers affair bureau "MAFF (Japanese Ministry of Agriculture, Forestry and Fisheries). The FSC specifies free sale status of the product in country of origin along with its availability. MAFF has its own specific format for COPP/FSC.

		Which could be verified from MAFF website: http://www.maff.go.jp/j/syouan/tikusui/yakuzi/170315.html. Evidence of approval status and applied formulation in country of origin of "Kyoto Biken" Cattlewin -5K(Inactivated) shall be confirmed from NVAL, MAFF Japan (reference regulatory authority) database/website available at https://www.vm.nval.go.jp/public/detail/15867 where it is mentioned that principal component of vaccine is as under: MDBK-NSC Cell Culture Cow Infectious Rhinotracheitis Virus No. 758-KB Strain (Seed) (Pre-Inactivated Virus Volume) 10 (8.5) TCID50 Or More / 1 Vial (20 ml) MDBK-NSC Cell Culture Cow Viral Diarrhea Virus Type 1 Nose-KB Strain (Seed) (Pre-Inactivated Virus Volume) 10 (8.1) TCID50 Or More / 1 Vial (20 ml) MDBK-NSC Cell Culture Cow Viral Diarrhea Virus Type 2 Kz-91-Kb Strain (Seed) (Pre-Inactivated Virus Volume) 10 (6.9) Tcid50 Or More / 1 Vial (20 ML) Mdbk-Nsc Cell Culture Cow Parainfluenza Type 3 Virus Bn1-1-Kb Strain (Seed) (Pre-Inactivated Virus Volume) 10 (8.4) Tcid50 Or More / 1 vial (20 ml) HMLU-SC Cell Culture Cow RS Virus Rs-52 Strain (Seed) (Pre-Inactivated Virus Volume) 10 (7.1) TCID Following documents are not submitted by the firm: a. Safety and efficacy studies. For this the firm has submitted that vaccine is a generic product it could be applied for approval as equivalent to the existing correspondent product such generic product is required to pass equivalency test by the NVAL (National Veterinary Assay Laboratory, as a result of test it is judged that essential biological nature, composition, usage, dosage, efficiency, viral nature are equivalent to the existing already approved product(infectious bovine rhinotracheitis, divalent bovine diarrhea, bovine parainfluenza, bovine RS virus infection combined inactivated adjuvanted vaccine) in spite of difference of virus strains.
	Evaluation by BE&R division.	Firm has submitted Efficacy study of commercial vaccine against Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Bovine Parainfluenza and Bovine Respiratory Syncytial Virus Infection, in a target specie experimental infection. **Conclusion:** The results of the study indicated that the Kyoto Biken,, Cattlewin-5k against Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Bovine Parainfluenza and Bovine Respiratory Syncytial Virus Infection is efficient in the prophylaxis of the Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Bovine Parainfluenza and Bovine Respiratory Syncytial Virus Infection in cattles, when the product is stored according to the leaflet instructions.
	Decision: In the light of opinion of Expert member Registration Board, that this vaccine is needed in imported animals & Keeping in view the legalized COPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

87.	**Name, address of Applicant / Importer**	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	**License No.**05-352-0066-100098D **Address**: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan **Validity:**17-Nov-2027

		Status: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economicand Technological Development Zone, Heilongjiang Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted original, Legalized CoPP (No. Heilongjiang 20220023) issued on 21-06-2022, valid upto 20-06-2024, issued by Heilongjiang Medical Products Administration, China. Legalized GMP Inspection Report issued by Heilongjiang Medical Products Administration, China.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific with brand name Globin Well I.V. inj letter of Authorization, from Harbin Pacific Biopharmaceutical Co., Ltd according to the letter, M/s. Harbin Pacific Biopharmaceutical Co., Ltd appoints Immunowell (Pvt) Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan It's representative for sole purpose of registration of the said product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. Dated: 02-Jan-2022
	Details of fee submitted	Rs.150, 000/- slip No.029922813 dated: 29-12-2022
	The proposed proprietary name / brand name	**Globin Well I.V. inj.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin IgG….. 2.5gm.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Intravenous Immunoglobulin
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2.5gm/50mL Vial

	Proposed unit price	Rs. 38,398/Vial
	Shelf Life	36 months
	Storage Conditions	$2^{O}C$ - $8^{O}C$
	The status in reference regulatory authorities	Gamimune 5% (Immune Globulin Intravenous) Approved by USFDA.
	For generic drugs (me-too status)	I.V. Globulin SN Injection registered in Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubility, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterization of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economicand Technological Development Zone, Heilongjiang Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Bulk solution of human immunoglobulin for intravenous injection is a transitional phase, so the stability studies are inapplicable.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted analytical methods as per in House Specs. Validation of analytical procedures, process validation, batch analysis and stability studies have been performed.
	Container closure system of the drug product	Injection vial made of molecule middle borosilicate glass, halogenated butyl rubber stopper for injection (brominated) and aluminum-plastic combination cap.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. The studies cover long term storage conditions (2°C - 8°C) for 36 months and accelerated storage conditions (25°C±2°C) 60%±5% RH for 6 months. Based on the results from the long term and accelerated stability studies, the proposed shelf life of 36 months at 2°C ± 8°C
	Module-IV	Not submitted
	Module-V	Not submitted
	Remarks	• Firm has not provided stability studies of drug substance with this justification that drug substance stability data is not required in china. • Firm has not provided safety and efficacy data with this justification that brands like Gamarrass, HL Globin and our product are being used in china from decades and their safety and efficacy is established for many decades. So Module IV and V are exempted.

Decision in 334th RB meeting:

Registration Board deferred the product for the following:

- For submission of Stability studies data of drug substance/evidence of ICH guideline indicating no requirement of stability data for this substance.
- For submission of safety and efficacy studies of applied formulation/ evidence of ICH guideline indicating no requirement of safety and efficacy data for applied formulation.

Response of firm:

1. Module IV and Module V have not been submitted.

Answer: As per "Form 5-F" and "Guidance document for submission of application on Form 5-F(CTD) for registration of Pharmaceutical Drug for Human Use" Module IV and Module V are optional., please find attached the Page No.39 of same Guidance. As per these guidance:

Module 4: (Non-clinical/ Safety)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 4 is optional.

Module 5: (Clinical/ efficacy)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 5 is optional".

Competitors of our product with same combination, strength and dosage form are already registered in all reference countries and with DRAP in many brands.

Therefore, on the basis of above explanations you are requested to include our Product Globin Well I.V. Inj. In upcoming Registration Board Meeting for the approval.

Decision in 336th RB meeting:

Registration Board after detailed deliberations deferred the product for submission of required data as per evaluator remarks.

Application of Finished Product, Local Manufacturing by M/s BF Biosciences Ltd, Raiwind, Lahore

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the firm has achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2022-2023** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board.

Molecule: Semaglutide

88.	**Name, address of Applicant / Importer**	**M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655ddress: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parenterals (Liquid & Lyophilized) For Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17970 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 11115303395)
	The proposed proprietary name / brand name	**Sematide 0.25mg/0.188mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.188mL contains: Semaglutide …..0.25mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1's (PFS)
	Proposed unit price	As per SRO
	Shelf Life	24 Months

	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **i) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP No. 223306B0/002018 Issue Dated: 16th August,2018 Firm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same	Firm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma

	concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance of following 3 batches at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable because of API import.
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.

	and finished product as required vide Rules 30 of Drug (LR&A) Rule.	
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of GD dated 31-10-2022 Form 6 dated 29-Sep 2022, commercial Invoice dated 16-09-2022 , Form 3 dated 16-09-2022 and Form 7 dated 16-09-2022 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each(working standard 100mg total).
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6months. Batch No. — Batch Size — Manufacturing date 020D03 — 680 PFS — March-2023 020D04 — 680 PFS — March-2023 020D05 — 680 PFS — March-2023
	Module IV	Detailed in sameness evaluation mentioned below
	Module V	Detailed in sameness evaluation mentioned below
	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:	
Biosimilarity parameters		**Sameness evaluation Data Submitted by M/s BF Biosciences Ltd**

Quality Comparison **1.** Physicochemical Characterization	Sematide Injection has been compared with Ozempic inj. Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **1. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION** **Comparative Testing with Ozempic Injection** (3.2.S.3.2 P 16 - 38) i) Peptide Sequence analysis by mass spectrometer (Primary Structure). ii) Circular dichroism spectrum analysis (Secondary structure). iii) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure). iv) Related substances/ Impurities by RP HPLC**.** v) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. vi) Biological activities (Cell line HEK - 293). vii) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **Primary Structure** i) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) ii) Amino Acid Analysis (3.2.S.3.1 - P. 6) ***Secondary Structure*** i) IR Spectrum (3.2.S.3.1 - P. 3) ii) UV Absorption (3.2.S.3.1 – P 4) iii) X-ray diffraction analysis (3.2.S.3.1 – P 14) iv) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **Sematide Injection (Manufactured by: BF Biosciences)** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:** **1. Primary Structure:** I) Complete peptide sequence Analysis by Mass Spectrometry. II) Peptide Mapping. **2. Secondary Structure:** I) Fourier Transform Infrared Spectrum. II) UV-Visible Spectrophotometer. **3. Physiochemical Test:** i) Appearance ii) Phenol content by RP HPLC. iii) pH. **4. Identification:** i) Identification by RP HPLC. ii) Molecular weight determination by SDS-PAGE. iii) Isoelectric point by IEF (Isoelectric Focusing). **5. Purity:**

	i) Subvisible Particles by Liquid Particle Counter. ii) Related Substances I by Reverse Phase HPLC. iii) Related Substances II by Reverse Phase HPLC. iv) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **6. Assay Testing:** i) Assay by Reverse Phase HPLC **7. Biological Activity and Determination of Protein Content:** i) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **8. Toxicity Testing:** i) Mammalian Erythrocytes Micronucleus Test **2. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*
Biological Activity	**Biological bioactivity** <u>Animal studies (Mutagenicity testing):</u> Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats(Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis ▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC) ▪ Related Substances I by RP HPLC ▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	

Impurities		Impurity Profiles **Impurities profile** ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies		The firm has submitted stability studies.
Non-Clinical studies		The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies		Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365 .**
		The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link:https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2
Proceeding of the 336th meeting; Registration Board agreed that the case will be decided in the light of evaluation of the Working Group narrated in the end of cases		
89.	**Name, address of Applicant / Importer**	**M/s BF Biosciences Ltd** **5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parenterals (Liquid & Lyophilized) For Biologicals & Non-Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17971 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 544248872559)
	The proposed proprietary name / brand name	**Sematide 0.5mg/0.375 mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.375mL contains Semaglutide 0.5mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1's (PFS)
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture,

		manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **ii) For Bulk Concentrate Import/Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP No. 223306B0/002018 Issue Dated: 16th August,2018 Firm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to	Not Applicable because of API import.

	manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of GD dated 31-10-2022 Form 6 dated 29-Sep 2022, commercial Invoice dated 16-09-2022 , Form 3 dated 16-09-2022 and Form 7 dated 16-09-2022 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each(working standard 100mg total).

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6 months. Batch No. Batch Size Manufacturing date 021D03 402 PFS March-2023 021D04 402 PFS March-2023 021D05 402 PFS March-2023
	Module IV	Detailed in sameness evaluation mentioned below
	Module V	Detailed in sameness evaluation mentioned below
	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:	

Biosimilarity parameters	**Sameness evaluation Data Submitted by M/s BF Biosciences Ltd**
Quality Comparison **1.** Physicochemical Characterization	Sematide Injection has been compared with Ozempic inj. Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **1. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION** Comparative Testing with Ozempic Injection (3.2.S.3.2 P 16 - 38) i) Peptide Sequence analysis by mass spectrometer (Primary Structure). ii) Circular dichroism spectrum analysis (Secondary structure). iii) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure). iv) Related substances/ Impurities by RP HPLC. v) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. vi) Biological activities (Cell line HEK - 293). vii) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **Primary Structure** i) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) ii) Amino Acid Analysis (3.2.S.3.1 - P. 6) ***Secondary Structure*** v) IR Spectrum (3.2.S.3.1 - P. 3) vi) UV Absorption (3.2.S.3.1 – P 4) vii) X-ray diffraction analysis (3.2.S.3.1 – P 14) viii) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **Sematide Injection (Manufactured by: BF Biosciences)** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:**

	1. Primary Structure: I) Complete peptide sequence Analysis by Mass Spectrometry. II) Peptide Mapping. **2. Secondary Structure:** I) Fourier Transform Infrared Spectrum. II) UV-Visible Spectrophotometer. **3. Physiochemical Test:** i) Appearance ii) Phenol content by RP HPLC. iii) pH. **4. Identification:** i) Identification by RP HPLC. ii) Molecular weight determination by SDS-PAGE. iii) Isoelectric point by IEF (Isoelectric Focusing). **5. Purity:** i) Subvisible Particles by Liquid Particle Counter. ii) Related Substances I by Reverse Phase HPLC. iii) Related Substances II by Reverse Phase HPLC. iv) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **6. Assay Testing:** i) Assay by Reverse Phase HPLC **7. Biological Activity and Determination of Protein Content:** i) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **8. Toxicity Testing:** i) Mammalian Erythrocytes Micronucleus Test **2. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*
Biological Activity	**Biological bioactivity** <u>Animal studies (Mutagenicity testing):</u> Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis

	▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC) ▪ Related Substances I by RP HPLC ▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	
Impurities	Impurity Profiles **Impurities profile** ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies	Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365.**
	The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link:https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2
Proceeding of the 336th meeting; Registration Board agreed that the case will be decided in the light of evaluation of the Working Group narrated in the end of cases	

90.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parentals (Liquid & Lyophilized) For Biologicals & Non-Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17972 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 582864826)
	The proposed proprietary name / brand name	**Sematide 1mg/0.75mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.75mL contains: Semaglutide…… 1mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1’s (PFS)
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **iii) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Dated: 16th August,2018 Firm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma
	The firm shall provide the lot release certificate of the	Not Applicable

	finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.

	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of GD, Form 6, commercial Invoice , Form 3 and Form 7 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C for 6 months. Batch No. — Batch Size — Manufacturing date 022D03 — 270 PFS — March-2023 022D04 — 270 PFS — March-2023 022D05 — 270 PFS — March-2023
	Module IV	Detailed in sameness evaluation mentioned below
	Module V	Detailed in sameness evaluation mentioned below
	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:	

Biosimilarity parameters	**Sameness evaluation Data Submitted by M/s BF Biosciences Ltd**
Quality Comparison **1.** Physicochemical Characterization	Sematide Injection has been compared with Ozempic inj. Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **1. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION** Comparative Testing with Ozempic Injection (3.2.S.3.2 P 16 - 38) i) Peptide Sequence analysis by mass spectrometer (Primary Structure). ii) Circular dichroism spectrum analysis (Secondary structure). iii) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure).

	iv) Related substances/ Impurities by RP HPLC**.** v) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. vi) Biological activities (Cell line HEK - 293). vii) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **1. Primary Structure** i) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) ii) Amino Acid Analysis (3.2.S.3.1 - P. 6) **2. Secondary Structure** i) IR Spectrum (3.2.S.3.1 - P. 3) ii) UV Absorption (3.2.S.3.1 – P 4) iii) X-ray diffraction analysis (3.2.S.3.1 – P 14) iv) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **Sematide Injection (Manufactured by: BF Biosciences)** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:** **1. Primary Structure:** I) Complete peptide sequence Analysis by Mass Spectrometry. II) Peptide Mapping. **2. Secondary Structure:** I) Fourier Transform Infrared Spectrum. II) UV-Visible Spectrophotometer. **3. Physiochemical Test:** i) Appearance ii) Phenol content by RP HPLC. iii) pH. **4. Identification:** i) Identification by RP HPLC. ii) Molecular weight determination by SDS-PAGE. iii) Isoelectric point by IEF (Isoelectric Focusing). **5. Purity:** i) Subvisible Particles by Liquid Particle Counter. ii) Related Substances I by Reverse Phase HPLC. iii) Related Substances II by Reverse Phase HPLC. iv) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **6. Assay Testing:** i) Assay by Reverse Phase HPLC **7. Biological Activity and Determination of Protein Content:** i) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **8. Toxicity Testing:** ii) Mammalian Erythrocytes Micronucleus Test **2. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*

Biological Activity	**Biological bioactivity** Animal studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats(Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis ▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC) ▪ Related Substances I by RP HPLC ▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	
Impurities	Impurity Profiles **Impurities profile** ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the in vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies	Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365** .

	The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link:https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2

Proceeding of the 336th meeting; Registration Board agreed that the case will be decided in the light of evaluation of the Working Group narrated in the end of cases

Evualtion of working group:

The task was assigned to working group of Mr. Muneeb Cheema, Deputy Director PE&R, & Mr. Muhammad Kashif, Deputy Director BE&R to evaluate the data submitted by the firm in the light of guidelines and present summarized data before the Registration Board for consideration of the case by the Board:

Summary of studies submitted by the Zhejiang Peptides Biotech Co., Ltd. Zhejiang China

C.T.D Reference	Requirements as per EMA Draft Guideline	Data provided by API manufacturer	USFDA Guideline Data Requirements
General Information 3.2.S.1	Nomenclature 3.2.S.1.1 (No additional requirements)	Recommended INN, Chemical Name, CAS No. and Company code	
	Structure 3.2.S.1.2	Chemical structure, three letter peptide sequence, molecular formula & molecular weight	
	General Properties 3.2.S.1.3 (Water content, isoelectric point, pH of a solution of the peptide, optical rotation, biological activity and solubility in different media, hygroscopicity with moisture sorption isotherms)	Appearance, solubility, hygroscopicity, specific optical rotation, pH, molecular wight, Polar Surface Area, Partition coefficient, particle size, Isoelectric point, polymorphism.	Attributes required for sameness of peptide: The proposed generic synthetic peptide is characterized to show the sameness of the active ingredient to that of the RLD with respect to the following properties: • Primary sequence and physicochemical properties, • Secondary structure, • Oligomer/aggregation states, and • Biological activity/function (by
Characterisation 3.2.S.3	Elucidation of Structure and other Characteristics 3.2.S.3.1 Sr. No / Tests / Analytical techniques 1. Molecular Mass / MS, LC-MS 2. Amino acid sequence / LC-MS/MS of intact molecule	MS, IR, UV, Elemental Analysis, Amino acid analysis (HPLC), X-ray diffraction analysis confirm amorphous form and TGA **Comparative testing with originator brand (Ozempic):** • Amino acid sequence analysis by	

		confirmation	LC-MS of enzymatically treated material (peptide mapping for long peptides)	UPLC-MS for primary structure; • Isoelectric point by capillary isoelectric focusing • Circular dichroism spectrum analysis by Chirascan Circular dichroism spectrometer confirms secondary structure • X-ray diffraction analysis confirm amorphous form	in vitro or animal studies);
		3. Secondary structure	Far-UV circular dichroism (CD) spectroscopy FT-IR spectroscopy		
		4. Tertiary structure	Near UV CD spectroscopy		
		5. Biological characterisation	Cell-based and other biological assays		
	<u>Physicochemical Characteristics:</u> Solubility and hygroscopicity studies, determination of the isoelectric point (pI) and thermogravimetric studies. Morphology by powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC) and light microscopy			Date of three batches submitted for appearance, solubility in various solvents & acid buffer solution, hygroscopicity, specific optical rotation, clarity and color of solution, pH, Molecular weight, particle size. Studies for morphology confirmation are recorded above.	
Impurities 3.2.S.3.2	<u>Peptide related impurities:</u> • starting materials; • formation during the manufacturing process; • resulting from degradation during the manufacturing process or during storage. <u>Inorganic impurities</u>			*<u>Peptide related impurities:</u>* Nine (09) process (peptide related) impurities may be generated and are defined in specification of final drug substance: Three peptide impurities are main impurities and limits ≤ 0.1% rest are potential impurities	Peptide related Impurities: Levels should same or lower for similar impurities in proposed generic / RLD. For new peptide impurities (an impurity not present in RLD): a. Levels should not be more than 0.1% b. Characterization of impurity (amino sequence and structure) and justification of not to affect the safety and effectiveness including immunogenicity.

	and limits are ≤ 0.2%. The total impurities are not more than 2%. Test results of validation batches confirmed the limits. *Inorganic impurities:* Ethyl isonitrosocyanoacetate(Oxyma), Hydroxylamine hydrochloride, -1-Hydroxybenzotriazole (HOBt), were used as condensation reagents are not detected in the final product. *Elemental impurities:* tested for the three validation batches and results are below 30% of the limits *Polymeric impurities/aggregates:* Not detected in the validation batches, limits defined ≤ 0.5%. *Residual Solvents:* Most of the solvents used during manufacturing process are not detected in final product rest are below the defined limits. Potential mutagenic impurities: N,N'-diisopropyl carbon diimide (DIC) used as condensation reagent and Ethyl 4-Bromobutyrate (From starting Material Fmoc-N(Gly- OtBu)Hmb Butyric Acid) are not detected in three validation batches. **Comparison of API and Originator Product (Ozempic)** *Related substances:* Four (04) impurities are detected in both	UHPLC-HRMS to detect and characterize the impurities peptide related impurities Other recommendations: FDA may recommend conducting additional comparative studies that can be submitted: *a. In vitro,* b. *In vivo* animal, c. Clinical PK/PD equivalence	

		API and original formulation: RRT0.754, RRT0.839, RRT0.897, RRT1.021, results of impurity RRT0.754RRT0.839、RRT1.021 in API are less than results in original formulation. Result of impurity RRT0.897 is comparable with result in original formulation. *Polymer:* No new polymers in Semaglutide API, which are not existed in original formulation. For polymer RRT0.876, which is detected in both Semaglutide API and originator formulation, result in Semaglutide API is much lower than result in original formulation. *Secondary structure by Circular dichroism spectrum analysis:* Far UV similarity value b/w API and originator formulation. *Biological activities with GLP1R receptor high express cell line:* The test results, relative activity of samples comparing with showed agonist activity onGLP-1 receptor in this study. *Isoelectric point with Imaging capillary isoelectric focusing electrophoresis (iCIEF):* Results are comparable *Thermoanalysis with DSC:*	

		Results are comparable
3.2. S.4	Appearance Identification; Amino acid analysis; Purity (total impurities; individual impurities (unspecified/specified); Aggregates / oligomers by SEC-HPLC (if relevant); Assay/content; e.g., by HPLC or elemental analysis; Acetic acid content/counter-ion content (residual) TFA content; pH of solution; Water content; Mass balance; Residual solvents; 464 Elemental impurities (e.g. in case of use of metal catalyst); 465 Bacterial endotoxins; Microbiological purity	Appearance, Solubility, Identification Molecular weight pH Color and clarity of solution Water content Amino acid analysis Sodium ion, carbonate ion, trifluoroacetic acid, acetic acid, Related substances Residual solvents Bacterial endotoxin Microbiological limit (TAMC, TYMC) Residual solvents Peptide content Assay

<u>Studies submitted by the Drug Product Manufacturer</u>

1. HPLC-MS

Comparative testing report is stipulated on request of BF BIOSCIENCES 5-KM, Sundar, Raiwind Road, Sundar Industrial Estate, Raiwind, Lahore, Punjab 54000, based on testing results obtained in Harvard Medical School, Taplin Mass Spectrometry Facility, 240 Longwood Ave. Boston, MA 02115 for received samples of Sematide Injection 1mg/0.75ml Batch# 022D03 and Ozempic Injection1.34mg/ml, Batch# MP5B060 Submitted on Sat. 01/13/2024 concluded following:

a. Comparative peptide sequence analysis between Sematide Injection and Ozempic Injection:
b. The automatic matching of secondary mass spectra (MS/MS) test data (peaklist) of sample and original product with theoretical amino acid sequence confirms that sequence of Sematide Injection is in accordance with sequence of original product.
c. Molecular weight determinatin by mass spectra was found same as 4111.16 Da for Sematide Injection and original product.

2. cAMP Hunter Semaglutide Bioassay Report

The study was conducted at Cancer Therapeutics Lab Department of Life Sciences, Syed Babar Ali School of Science and Engineering (SBASSE), Lahore University of Management Sciences (LUMS) on 12.01.2024. the study concluded nearly identical graph curves for the control drug Ozempic and the test sample at two tested concentrations. The EC_{50} for the lower concentration of the Sematide sample was 0.1093 ng/mL, which is similar to 0.1003 ng/mL for the higher concentration. Both these values show a marked similarity to the value for Ozempic, which is 0.1091 ng/mL. This shows that Sematide is as effective as Ozempic in GLP1R activation in this assay.

3. High dose toxicity studies: Mammalian Erythrocyte Micronucleus Test on 6mg/mL of Semaglutide

The study was conducted at National Center of Excellence in Molecular Biology, University of the Punjab, Lahore on 31.01.2024. The study was performed to analyze and compare the effect of 6X dose concentration of Semaglutide. Bone marrow was taken and slide prepared and stained with Gimsa stain to observe the immature erythrocyte population and morphology of the cells. It was observed that both control and test samples showed similar count of immature erythrocytes.

4. Pharmacokinetic study of sematide in non-clinical species (Albino Rats)

The study was conducted at National Center of Excellence in Molecular Biology, University of the Punjab, Lahore on 12.02.2024 to 10.03.2024. the study attributes include, Cmax, AUC, Tmax, Bioavailability, Steady sate conc., volume of distribution, plasma protein binding, drug stability, GLP-1 function, role of pancreatic hormones, sematide action, GLP-1 receptor binding and elimination. The executive summary is as under:

" *Pharmacokinetics study was performed to analyze and compete the effects of different sematide in nonclinical animals (rats) Sematide was injected to tats and also the bioavailability of sematide in blood and also elimination concentration of drugs into urine by performing ELISA method. Complete data of 28 days experiment was made an interpretive by statistical analysis (Descriptive Statistics). Graph shows the bioavailability of sematide in blood for days. Intact sematide in urine accounted for less than 1% in rats"*

Proceedings of the Board. The evaluation of the working group was presented along with the studies submitted by firm in details. Members of Registration board appreciated the efforts of the firm for conduction of analysis of Product from different renowned institutes and recommended the product for approval.

Decision: Registration Board considered the data submitted by the applicant with regard to attributes required for the sameness of peptide and peptide related impurities by the drug substance manufacturer and drug product manufacturer. As the data submitted by the firm is in line with the requirements laid down in guidance documents framed by the United States Food & Drug Administration, hence the Board approved the grant of registration of Sematide 0.25, 0.5 and 1mg Injection (Semaglutide) subject to following conditions namely;

a. The firm will perform the post marketing surveillance studies.
b. The firm will make arrangements for the ADR reporting as per Rules.
c. The firm will submit the quarterly safety Reports to the Registration Board.

CASES OF DD-IV (MS. ANAM SAEED)

A Locally manufactured Human Biological applied by M/s SAMI Pharmaceuticals (Pvt.) Ltd., Karachi

91.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Details of Drug Manufacturing License	DML No:000072 Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 715/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. 14911 Dated 13-06-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN R 100 IU/ml Injection (rDNA origin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ……100IU (rDNA origin) Ph. Eur. Specs
	Pharmaceutical form of applied drug	Colorless liquid, free from turbidity and foreign matter

	Pharmacotherapeutic Group of (API)	Insulin and analogues for injection, fast acting ATC: A10AB01
	Reference to Finished product specifications	Ph. Eur. Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	HUMULIN S (Soluble) 100IU/ml solution for injection in cartridge by Eli Lilly UK, MHRA approved
	For generic drugs (me-too status)	Actrapid – HM Penfills by M/s Novo Nordisk, Reg. No. 010344
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20˚C ± 5˚C for 60 months Accelerated: 5˚C ± 3˚C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G).
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary Packaging is 3mL glass cartridge Type I with rubber disc seal and Bromobutyl rubber plunger head with secondary packaging unit carton
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C/

		60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest European Pharmacopoeia of three trial batches of Finished Pharmaceutical Product. • In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.
Decision: Registration Board deferred the case for submission of the following. • **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).** • **Bio-similarity data as per WHO Bio similarity guidelines.**		

92.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi**
	Details of Drug Manufacturing License	DML No:000072 Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 713/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. 14910 Dated 13-06-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN-NPH 100 IU/ml Injection Isophane Suspension (rDNA origin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ……100IU (rDNA origin) Ph. Eur. Specs
	Pharmaceutical form of applied drug	White or almost white suspension which on standing deposits a white or almost white sediment and leaves a colorless or almost colorless supernatant; the sediment is readily suspended by gently shaking
	Pharmacotherapeutic Group of (API)	Insulins and analogues for injection, Intermmediate-acting ATC: A10AC01
	Reference to Finished product specifications	Ph. Eur. Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin I 100 IU/ml Suspension for Injection in Cartridge, MHRA approved
	For generic drugs (me-too status)	Insulatard-HM Penfills by M/s Novo Nordisk, Reg. No. 010341
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20˚C ± 5˚C for 60 months Accelerated: 5˚C ± 3˚C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product..
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary packaging is 3mL clear glass vial, bromo-butyl rubber stopper and aluminum seal with secondary packaging of unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C/ 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest Ph.Eur Pharmacopoeia of three trial batches of Finished Pharmaceutical Product. • In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.
Decision: Registration Board deferred the case for submission of the following; • **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).** • **Bio similarity data as per WHO Bio similarity guidelines.**		

93.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**

	Details of Drug Manufacturing License	DML No:000072 Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 711/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. 14909 Dated 13/06/2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN 70/30 *(Human Insulin rDNA origin)* Biphasic 100IU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ….100 IU [70% Human Insulin Isophane Suspension, 30% Human Insulin Injection (rDNA Origin)] Ph. Eur. Specs
	Pharmaceutical form of applied drug	A white or almost white suspension which on standing deposits a white or almost white sediment and leaves a colorless or almost colorless supernatant; the sediment is readily suspended by gently shaking
	Pharmacotherapeutic Group of (API)	Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting ATC: A10A D01
	Reference to Finished product specifications	Ph. Eur. Specs.

	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin M3 100 IU/ml suspension for injection in cartridge, MHRA Approved
	For generic drugs (me-too status)	Mixtard 30 HM by M/s Novo Nordisk, Reg. No. 010346
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted..
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20°C ± 5°C for 60 months Accelerated: 5°C ± 3°C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary packaging is 3mL clear glass vial, bromo-butyl rubber stopper and aluminum seal with secondary packaging of unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03

	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest Ph.Eur Pharmacopoeia of three trial batches of Finished Pharmaceutical Product. • In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.
Decision: Registration Board deferred the case for submission of the following; • **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).** • **Bio similarity data as per WHO Bio similarity guidelines.**		

B **<u>Imported Veterinary Biological Drugs applied by M/s U.M. Enterprises, Karachi</u>**

94	**Name of Applicant**	U.M. Enterprises, Plot # 12, Sector 15 Korangi Industrial Area, Karachi, Pakistan.
	DSL details	DSL License No. 313 valid up to 23-02-2028.
	Name of Manufacturer	**Phibro Animal Health Limited.** Address: Finisklin Bussiness Park, Sligo F91 R772, Ireland.
	Name of exporting country	**Ireland**
	Brand Name + Dosage Form + Strength	**Phivax IB VAR 206** **Effervescent Tablet for suspension** Each dose contains: Live attenuated Avian infectious bronchitis virus, variant 206 strain…… $\geq 10^{3.2}$ EID_{50}
	Composition	Each dose contains: Live attenuated Avian infectious bronchitis virus, variant 206 strain.… $\geq 10^{3.2}$ EID_{50}
	Finished product specifications	Innovator's specification
	Pharmacological Group	Live Vaccine
	Shelf life	18 Months (Store at 2ºC to 8ºC)
	International availability	Latvia, Romania, Czech Republic, Bulgaria, Slovakia, Slovenia, Poland, Turkey, Russia, Uzbekistan, Israel, Azerbaijan, Mexico, South Africa, United Arab Emirates, Iran, Brazil, Ukraine
	Alternate Products already registered in Pakistan	The applied strain is not registered as per data available
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A DRAP R&I: 31963 dated 22-11-2021. Fees of PKR 150,000/- (Deposit slip # 6178111188 dated 14-10-2021)
	Demanded Price Pack size	Decontrolled Pack size not mentioned in application.
	General Documentation	1. Legalized Certificate of Pharmaceutical Product 2. Legalized GMP Certificate

		3. Legalized Distribution Agreement.
	Evaluator Comments	• COPP does not indicate the free sale status of the product in country of origin. • Only applicant details are mentioned in COPP. Manufacturer or MA Holder details are not mentioned anywhere in COPP • The applied strain is not registered here as per data available. • Pack size is not mentioned in the application. • The product monograph is available in European Pharmacopoeia but the firm has not performed all the tests as per pharmacopoeia. • Stability studies are conducted at 0,6,12,15 and 18 months.
	Decision: Registration Board, after detailed deliberation, referred the product to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan. **Moreover, the Board advised BE&R Division to ask the applicant to submit following data;** • **Notrised COPP indicating free sale status, details of manufacturer and MA Holder.** • **Submission of specifications, analytical procedures and COAs as per official pharmacopoeia.** • **Detail about pack size of the applied product and stability data of that pack size at recommended time intervals.**	

C Miscellaneous Cases:

Imported Human Biological (Heparin) deferred in 332nd meeting of Registration Board

95	Name, address of Applicant / Marketing Authorization Holder	**M/s Hakimsons (Impex) (Pvt.) Ltd.,** Address: Hakimsons Building, 19 T-30 West Wharf Road Karachi 74000 Pakistan
	Product license holder	LABORATORIOS FARMACEUTICOS ROVI, S.A. Julián Camarillo, 35 28037 Madrid – Spain
	Name, address of Manufacturing site.	**Manufacturing and primary and secondary packaging site of the finished product;** ROVI PHARMA INDUSTRIAL SERVICES, S.A. Paseo de Europa, 50, San Sebastian de los Reyes 28703 Madrid-Spain **Batch control and batch Release site;** ROVI PHARMA INDUSTRIAL SERVICES, S.A./ Julián Camarillo, 35 28037 Madrid – Spain **Marketed by;** Merilios Global Private Ltd. 16th Floor, Hoechst House, Nariman Point, Mumbai- 400-021, Maharashtra, India.
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The firm has submitted Legalized COPP # 2022/01665 issued on 06/2022.
	Details of letter of authorization / sole agency agreement	The firm has submitted Supply and Distribution Agreement between M/s Merilios Global Private Ltd. India and M/s Hakimsons (Impex) (Pvt.) Ltd., Karachi which is not product specific.

	Status of the applicant	☒ Importer ☐ Manufacturer ☐ Is involved in none of the above (contract)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Diary No. 982 dated 18th October 2023.
	Details of fee submitted	PKR 150000.0/- Dated 27/09/2023
	The proposed proprietary name / brand name	**Heparin Rovi 1000 IU/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Heparin Sodium…….5000 IU
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Injectable anticoagulants drugs (B01A2), ATC Code: B01AB, antithrombotic
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	1's Vial (5mL)
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Heparin Sodium Solution for injection 1000IU/ml is Registered in the country of the origin Spain. Drug Name: HEPARIN SODIUM, API: HEPARIN SODIUM, Strength: 10,000 IU/ml. Dosage Form: INJECTABLE;INJECTION, Company Name: FRESENIUS KABI USA
	For generic drugs (me-too status)	Gratin Inj, 1000IU/ml, Reg. No. 085774
	GMP status of the Finished product manufacturer	Firm has submitted Legalized GMP certificate (ES//110HVI/2Ib) valid till dated 03-06-2024
	Name and address of API manufacturer.	Yantai Dongcheng Biochemical Co., Ltd. No.07, Changbaishan Road, Yantai Development Zone, Shandong Province, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

<table>
<tr><td></td><td>Stability studies</td><td>Stability study conditions:
Real time: 25°C ± 2°C / 60 ± 5%RH
Accelerated: 40°C ± 2°C / 75 ± 5%RH
Batches: (Real time: 25 ± 2 °C / 60 ± 5%RH
Accelerated: 40°C ± 2°C / 75 ± 5%RH)</td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and Stability.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product.</td></tr>
<tr><td></td><td>Container closure system</td><td>Vial: Type I glass (European Ph. <3.2.1.>).
Stopper: Bromobutyl rubber elastomer Type I (European Ph. <3.2.9.>).
Coloured aluminium protective cap.</td></tr>
<tr><td></td><td>Stability data of Drug Product</td><td>The firm has submitted stability study data of 3 batches under following conditions:
Accelerated, 6 months, 40°C ± 2°C/ 75%±5%RH
Intermediate, 36 months, 30°C ± 2°C/ 65%±5%RH
<table><tr><td>Batch no.</td><td>Batch size</td><td>Mfg. date</td></tr><tr><td>110501</td><td>42 L (Pilot batch)</td><td>Dec. 2011</td></tr><tr><td>110502</td><td>350 L (Ind. Batch)</td><td>Dec. 2011</td></tr><tr><td>110503</td><td>350 L (Ind. Batch)</td><td>Dec. 2011</td></tr></table></td></tr>
<tr><td></td><td>Remarks</td><td>The firm has claimed Ph. Eur. Specifications while the product is available in British Pharmacopoeia.</td></tr>
<tr><td></td><td>Decision of RB in its 331st meeting</td><td>Registration Board deferred the case for clarification of finished product specifications and details of exporting country.</td></tr>
<tr><td></td><td>Decision of RB in its 332nd meeting</td><td>The case was discussed in 331st meeting and deferred for clarification regarding finish product specification. No response received from the firm. Registration Board again deferred the case for clarification of finished product specifications (as the product is available in British Pharmacopoeia, while the firm requested for Ph. Eur. Specification) and role of marketed by. As it is mentioned on Form-5 that the product is marketed by Merilios Global Private Ltd. 16th Floor, Hoechst House, Nariman Point, Mumbai- 400-021, Maharashtra, India.</td></tr>
<tr><td></td><td>Remarks by DBE&R</td><td>The firm has submitted the following clarifications;
• The firm stated that our product's API complies with the European Pharmacopoeia and the finished product's specification is In-House.
• The firm has submitted Ministry of Foreign Affairs attested Deed of Adherence, Related to the License and Supply Agreement, between Hakimsons, Rovi and Merilios Global wherein it is stated that ROVI granted MERILIOS the exclusive license to use the Proprietary Information contained in the Registration dossier, pertaining to the product, in order to obtain a marketing</td></tr>
</table>

		authorization for the product in its own name and on its own behalf in the territory of Pakistan. ROVI and MERILIOS agreed that MERILIOS shall be entitled to appoint nominees (e.g. Hakimsons) for the commercialization of the product in the territory of Pakistan and to hold the regulatory approvals and the marketing authorizations on its behalf. The Letter of Authorization/ Supply and Distribution Agreement submitted by the firm is issued by M/s MERILIOS, INDIA which is also not product specific.
Decision: On the basis of documents/information/data along with legalized COPP submitted by the applicant, indicating product availability in the country of origin (Spain), Registration Board approved the product subject to compliance to current import policy for finished drugs.		

Locally Manufactured Human Biological i.e. Semaglutide Injection applied by M/s Macter International Limited approved in 331st RB meeting

96	Name, address of Applicant / Importer	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Formulation Filling (Local Manufacturing)
	Dy. No. and Date of submission	Dy.No. 4861 (R&I) dated 20-02-2022
	Details of fee submitted	PKR.30,000/- (Slip # 10008463700018)
	The proposed proprietary name / brand name	**Seglutide 2mg/1.5ml vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains 1.34 mg of semaglutide. (i.e. 2 mg / 1.5 ml per vial)
	Pharmaceutical form of applied drug	Solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	1's vial
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, ferozmanufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **iv) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Dated: June-02-2022 GMP Valid Dated: June-01-2024 Firm has submitted the GMP issued by People's Republic of China, Qingyoun City Qingcheng District ShijiaoTow, China

	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of concentrated bulk drug substance at accelerated and real time conditions. The accelerated stability data is conducted at 5°C ± 3°C for 6 months, and the real time stability data is conducted Under -20°C ± 5°C for 24 months. Batch No: SM-2101002 Batch No: SM-2101003 Batch No: SM-2103004
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Submitted**
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.

<table>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted details of analytical method validation.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>3 ml USP type 1 clear glass vials accompanied with 13 mm slit less siliconized butyl grey rubber stoppers and aluminum flip off seal.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP</td><td>The firm has submitted copy of GD, form 6 & invoice specifying the import of 10gram of semaglutide.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C for 6 months.
<table><tr><td>Batch No.</td><td>Batch Size</td><td>Manufacturing date</td></tr><tr><td>SEMA-01A</td><td>200 vials</td><td>15-04-2022</td></tr><tr><td>SEMA-02A</td><td>200 vials</td><td>19-04-2022</td></tr><tr><td>SEMA-03A</td><td>200 vials</td><td>21-04-2022</td></tr></table></td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td colspan="2">The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:</td></tr>
<tr><td colspan="2">Biosimilarity parameters</td><td>Sameness evaluation Data Submitted by M/s Macter International Limited.</td></tr>
<tr><td colspan="2">Quality Comparison
2. Physicochemical Characterization</td><td>Seglutide Injection has been compared with Ozempic inj. Reference Listed Drug (RLD)
The quality attributes characterize biological products in terms of structural, physicochemical and functional properties.
E. Primary sequence and physicochemical properties
F. Secondary structure
G. Oligomer/aggregation states
H. Biological activities (by in-vitro or animal studies)
Sameness studies
3. Structural comparison
Following robust characterization of drug substance and drug product proves the sameness of Seglutide with RLD.
<u>Primary Structure</u>:
• Complete peptide sequence analysis by mass spectrometry
• Peptide mapping
• Peptide coverage map
• N terminal sequence analysis
• Molecular weight by high resolution mass spectrometry
<u>Secondary Structure</u>:
• IR Spectrum
• UV absorption
See Annex 6.7
4. Quality:
• Chiral analysis
• Elemental analysis
• Capillary isoelectric focusing
• Physiochemical properties
• Hygroscopicity</td></tr>
</table>

	• Comparative testing of Seglutide with RLD • Identification by RP HPLC • Related Substances by RP HPLC • Identification and molecular weight determination bybTris Tricine SDS – Page • Protein content & Binding assay by ELISA • Determination of HMW proteins by Size Exclusion Chromatography • Determination of Specific activity
Biological Activity	Biological bioactivity A. Animal studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. Comparative studies done by Macter: • Drug Substance: • Physical appearance • Water Content • Assay • RP HPLC • Specific bioactivity • Identification • RP-HPLC • Peptide mapping • Tris Tricine SDS PAGE • Purity • High molecular weigh proteins • Related Substances • Residual Solvents • N,N – Dimethyl formamide • Tetrahydrofuran • Dichloromethane • Ethanol • N,N disopropylethylamine • Safety • BET • Microbial Limits • Aerobic count • Yeast & mould count • Escherichia Coli
Immunochemical properties	
Impurities	Impurity Profile • Peptide-related impurities • Hydrophilic and hydrophobic impurities • High molecular weight protein impurities • Process related impurities • HCP & HCDNA • Intermediate residue and reaction by products • Inorganic and ion impurities • Residual solvents

	• Elemental impurities
	• Genotoxic impurity
	• Residual host cell DNA
	• Nitrosamine impurities
	  • By process
	  • By contamination
	  • By degradation
	  • By packing material
	  • Antibiotic residues
	  • Degradation impurities
	  • Isomeric
	  • Dipeptide+oxidative impurities
	  • Isomer & hydrolytic impurities.
	  • High Temperature and high humidity degradation.

Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	Not submitted
Clinical Studies	Not submitted

Evaluation by BE&R:

Sr. No.	Deficiencies	Response by the firm
1.	The submitted commercial invoice for the import of Semaglutide is not cleared by assistant director (I & E) of respective field office.	System generated Form 6 and Good Declaration Certificate attached.
2.	Provide result of all quality parameter in comparative analysis of developed formulation with innovator product as the submitted report comprises of reduced testing.	The firm has submitted comparative analysis of test product with innovator Ozempic (Batch# MP5A069) has been carried out on following parameters and all satisfactory results indicate that our product resemble to Innovator product. The parameters include Dosage form, Strength, Route of administration, Physical Appearance, pH, Particulate Matter, Identification by HPLC, Molecular Wight (SDS PAGE), Assay by RP HPLC, Specific Activity by Biological Assay, Protein content by ELISA, Phenol Content, Impurities (Hydrophilic Impurities, Hydrophobic Impurities, Total impurities), Aggregates (high molecular weight proteins), Sterility test, Endotoxin test.
3.	Justify container closure system of USP type I clear glass vial while innovator product Ozempic is packaged in multi dose cartridge single patient pen injector.	Product contact parts in both cases are same i.e. Class 1 clear glass in cartridge used in RLS and same class 1 glass vial is used in Seglutide. Stability studies indicate no interaction of primary packing with product.
4.	Submit legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate /ready to fill bulk of biological drug to Pakistani manufacturer for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Direct link of GMP inspection report of national regulatory authority of exporting country is provided of the drug substance manufacturer.
5.	Submit legalized free sale certificate/CoPP either from country of origin or by any	Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not

	reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to concerned authority.	applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
6.	Submit the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity	Following criteria of sameness evaluation has been used. Detailed report is attached. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by in vitro or animal studies <u>Semaglutide is not a protein by the definition of USFDA. It is a peptide.</u> Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/ tertiary and quaternary structures which cannot be fully elucidated by analytical means that's why clinical evidences are required to prove the efficacy and safety. Biosimilarity applies mostly to protein based therapeutics. 21 CFR 600.3(h)(6) defines a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. (Annex 5. page 2, para 2) <u>Semaglutide is peptide which is included in complex APIs & complex product</u> Semaglutide which is comprised of 31 amino acids (less than 40) is not a protein is categorized as complex API and due to complex active and drug product containing small peptide is defined ad complex product. (Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA, Guidance for Industry issued in October 2022). (see Annex 7, page 3 para 2). <u>Waiver of *In-vivo* bioequivalence by **USFDA** product specific guideline</u> Product Specific Guideline on Semaglutide (annex 6.1) has described the conditions to qualify for submitting an waiver of in vivo bioequivalence (BE) study on the basis that BE is self-evident under 21 CFR 320.22(b (annex 6.2)), a generic Semaglutide subcutaneous solution for injection product should qualitatively (Q1) and quantitatively (Q2) be the same as the Reference Listed Drug (RLD).
7.	Provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export	Not applicable.

8.	Submit justification for not performing all test mentioned on Certificate of analysis	Complete analysis has been performed on following parameters. **Comparative COA is attached**
9.	Provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Agreement with DS manufacturer has been attached

Previous Decision: Registration Board after thorough deliberation decided to defer for the documents / information as under **(M-329)**:

The firm shall submit evidence (legalized FSC/CoPP/Registration certificate) of finished product manufactured by same concentrate/ready to fill bulk. either from country of origin or by any reference regulatory authority as adopted by Registration Board.

Evaluation by BE&R: The firm has submitted that Semaglutide is being supplied as intermediate bulk for which issuance of FSC / COPP / Registration certificate is not issued by country of origin, hence COPP/FSC is not accessible

Drug Substance manufacturer i.e Livzon New North River Pharmaceutical Co., Ltd. is GMP compliant facility, which manufacture API i.e., Semaglutide.

Moreover, as per the prevalent format of FSC / CoPP (WHO COPP scheme) / Registration certificate of finished product, name of Drug substance manufacturer is not mentioned.

Drug Substance manufacturer i.e Livzon New North River Pharmaceutical Co., Ltd had exported Semaglutide to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.

About 20 different Drug Products of Semaglutide are already registered in Bangladesh and freely available in the market, the same can be verified from official website link.

https://dgdagov.info/index.php/registered-products/allopathic

Discussion of RB in 331st meeting: The Board was apprised that the firm has performed sameness evaluation data as per FDA criteria as below:

Primary Sequence & Physicochemical properties:

- Complete peptide sequence analysis by Mass spectrometry
- Molecular weight determination by Tris Tricine SDS-PAGE

Secondary Structure

- By circular Di-Chroism
- By Capillary Iso-electric focusing

Oligomeric states

- High molecular weight proteins by Size exclusion chromatography (SEC)

Biological activities

- Determination of specific activity by in-vitro Bioassay
- Protein content by ELISA

Decision: On the basis of documents/information/data along with sameness evaluation data as per FDA criteria and comparative testing with innovator product (Ozempic 2mg/1.5ml PFS of Novo Nordisk A/S), Registration Board approved the registration of Seglutide 2mg/1.5ml vial. The firm shall submit the non-clinical and clinical data of semaglutide finished product developed from same biological substance manufacturer i.e., Livzon.

Evaluation by DB&R:

The firm has submitted the following;

- Single dose toxicity studies of Seglutide injection 1.34mg/ml versus Ozempic (Reference) conducted in 20 mice at M/s Dow University of Health Sciences, Karachi.
- A single dose, randomized, open label, parallel controlled pharmacokinetic Phase-I Clinical trial of Semaglutide Injection versus Ozempic in 64 healthy subjects.

The firm has not provided the COPP of finished product manufactured from same concentrate/ready to fill bulk.
Decision: The Registration Board endorsed its earlier decision of 331st Meeting

97	Name, address of Applicant / Importer	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local repacking
	Name, address of manufacturer(s)	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Formulation Filling (Local Manufacturing)
	Dy. No. and Date of submission	Dy.No. 4862 (R&I) dated 20-02-2022
	Details of fee submitted	PKR.30,000/- (Slip # 10008463700018)
	The proposed proprietary name / brand name	**Seglutide 4mg/3ml vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains 1.34 mg of semaglutide. (i.e. 4 mg / 3 ml per vial)
	Pharmaceutical form of applied drug	Solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's vial
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2°C – 8°C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 4 mg/3ml (USFDA Approved)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107914)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **v) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Date : June-02-2022 GMP Valid Date : June-01-2024 Firm has submitted the GMP issued by People's Republic of China, Qingyoun City Qingcheng District ShijiaoTow .
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of concentrated bulk drug substance at accelerated and

		real time conditions. The accelerated stability data is conducted at 5°C ± 3°C for 6 months, and the real time stability data is conducted Under -20°C ± 5°C for 24 months. Batch No: SM-2101002 Batch No: SM-2101003 Batch No: SM-2103004
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Submitted**
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm has submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	3 ml USP type 1 clear glass vials accompanied with 13 mm slit less siliconized butyl grey rubber stoppers and aluminum flip off seal.
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of GD, form 6 & invoice specifying the import of 10gram of semaglutide.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C for 6 months.

		<table><tr><td>Batch No.</td><td>Batch Size</td><td>Manufacturing date</td></tr><tr><td>SEMA-01B</td><td>200 vials</td><td>26-04-2022</td></tr><tr><td>SEMA-02B</td><td>200 vials</td><td>27-04-2022</td></tr><tr><td>SEMA-03B</td><td>200 vials</td><td>28-04-2022</td></tr></table>
	Module IV	Detailed in sameness evaluation mentioned below
	Module V	Detailed in sameness evaluation mentioned below
	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:	

WHO Biosimilarity Guidelines	**sameness evaluation** **Data Submitted by M/s Macter International Limited.**
Quality Comparison **3.** Physicochemical Characterization	Seglutide Injection has been compared with Ozempic inj Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. I. Primary sequence and physicochemical properties J. Secondary structure K. Oligomer/aggregation states L. Biological activities (by in vitro or animal studies) **Sameness studies** **5. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Seglutide with RLD. Primary Structure: • Complete peptide sequence analysis by mass spectrometry • Peptide mapping • Peptide coverage map • N terminal sequence analysis • Molecular weight by high resolution mass spectrometry Secondary Structure: • IR Spectrum • UV absorption See Annex 6.7 **6. Quality**: • Chiral analysis • Elemental analysis • Capillary isoelectric focusing • Physiochemical properties • Hygroscopicity • Comparative testing of Seglutide with RLD • Identification by RP HPLC • Related Substances by RP HPLC • Identification and molecular weight determination bybTris Tricine SDS – Page • Protein content & Binding assay by ELISA • Determination of HMW proteins by Size Exclusion Chromatography • Determination of Specific activity
Biological Activity	Biological bioactivity B. Animal studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents.

	Comparative studies done by Macter:
	• Drug Substance:
	  • Physical appearance
	  • Water Content
	  • Assay
	  • RP HPLC
	  • Specific bioactivity
	  • Identification
	  • RP-HPLC
	  • Peptide mapping
	  • Tris Tricine SDS PAGE
	  • Purity
	  • High molecular weigh proteins
	  • Related Substances
	  • Residual Solvents
	  • N,N – Dimethyl formamide
	  • Tetrahydrofuran
	  • Dichloromethane
	  • Ethanol
	  • N,N disopropylethylamine
	  • Safety
	  • BET
	  • Microbial Limits
	  • Aerobic count
	  • Yeast & mould count
	  • Escherichia Coli

Immunochemical properties	Not submitted.

Impurities	<u>Impurity Profile</u>
	• Peptide-related impurities
	  • Hydrophilic and hydrophobic impurities
	• High molecular weight protein impurities
	• Process related impurities
	  • HCP & HCDNA
	• Intermediate residue and reaction by products
	• Inorganic and ion impurities
	• Residual solvents
	• Elemental impurities
	• Genotoxic impurity
	• Residual host cell DNA
	• Nitrosamine impurities
	  • By process
	  • By contamination
	  • By degradation
	  • By packing material
	  • Antibiotic residues
	  • Degradation impurities
	  • Isomeric
	  • Dipeptide+oxidative impurities
	  • Isomer & hydrolytic impurities.
	  • High Temperature and high humidity degradation.

Stability Studies	The firm has submitted stability studies.
Non-clinical Studies	Not submitted

Clinical Studies	Not Submitted

Evaluation by BE&R:

Sr. No.	**Deficiencies**	**Response by the firm**
1.	The submitted commercial invoice for the import of Semaglutide is not cleared by assistant director (I & E) of respective field office.	System generated Form 6 and Good Declaration Certificate attached.
2.	Provide result of all quality parameter in comparative analysis of developed formulation with innovator product as the submitted report comprises of reduced testing.	The firm has submitted comparative analysis of test product with innovator Ozempic (Batch# MP5A069) has been carried out on following parameters and all satisfactory results indicate that our product resemble to Innovator product. The parameters include Dosage form, Strength, Route of administration, Physical Appearance, pH, Particulate Matter, Identification by HPLC, Molecular Wight (SDS PAGE), Assay by RP HPLC, Specific Activity by Biological Assay, Protein content by ELISA, Phenol Content, Impurities (Hydrophilic Impurities, Hydrophobic Impurities, Total impurities), Aggregates (high molecular weight proteins), Sterility test, Endotoxin test.
3.	Justify container closure system of USP type I clear glass vial while innovator product Ozempic is packaged in multi dose cartridge single patient pen injector.	Product contact parts in both cases are same i.e. Class 1 clear glass in cartridge used in RLS and same class 1 glass vial is used in Seglutide. Stability studies indicate no interaction of primary packing with product.
4.	Submit legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate /ready to fill bulk of biological drug to Pakistani manufacturer for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Direct link of GMP inspection report of national regulatory authority of exporting country is provided of the drug substance manufacturer.
5.	Submit legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to concerned authority.	Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
6.	Submit the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity	Following criteria of sameness evaluation has been used. Detailed report is attached. E. Primary sequence and physicochemical properties F. Secondary structure G. Oligomer/aggregation states H. Biological activities (by in vitro or animal studies

		Semaglutide is not a protein by the definition of USFDA. It is a peptide. Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/ tertiary and quaternary structures which cannot be fully elucidated by analytical means that's why clinical evidences are required to prove the efficacy and safety. Biosimilarity applies mostly to protein based therapeutics. 21 CFR 600.3(h)(6) defines a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. (Annex 5. page 2, para 2) Semaglutide is peptide which is included in complex APIs & complex product Semaglutide which is comprised of 31 amino acids (less than 40) is not a protein is categorized as complex API and due to complex active and drug product containing small peptide is defined ad complex product. (Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA, Guidance for Industry issued in October 2022). (see Annex 7, page 3 para 2). Waiver of *In-vivo* bioequivalence by **USFDA** product specific guideline Product Specific Guideline on Semaglutide (annex 6.1) has described the conditions to qualify for submitting an waiver of in vivo bioequivalence (BE) study on the basis that BE is self-evident under 21 CFR 320.22(b (annex 6.2)), a generic Semaglutide subcutaneous solution for injection product should qualitatively (Q1) and quantitatively (Q2) be the same as the Reference Listed Drug (RLD).
7.	Provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export	Not applicable.
8.	Submit justification for not performing all test mentioned on Certificate of analysis	Complete analysis has been performed on following parameters. **Comparative COA is attached**
9.	Provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Agreement with DS manufacturer has been attached

Previous Decision: Registration Board after thorough deliberation decided to defer for the documents / information as under **(M-329)**:

The firm shall submit evidence (legalized FSC/CoPP/Registration certificate) of finished product manufactured by same concentrate/ready to fill bulk either from country of origin or by any reference regulatory authority as adopted by Registration Board.

Evaluation by BE&R: The firm has submitted that Semaglutide is being supplied as intermediate bulk for which issuance of FSC / COPP / Registration certificate is not issued by country of origin, hence COPP/FSC is not accessible

Drug Substance manufacturer i.e Livzon New North River Pharmaceutical Co., Ltd. is GMP compliant facility, which manufacture API i.e., Semaglutide.

Moreover, as per the prevalent format of FSC / CoPP (WHO COPP scheme) / Registration certificate of finished product, name of Drug substance manufacturer is not mentioned.

Drug Substance manufacturer i.e Livzon New North River Pharmaceutical Co., Ltd had exported Semaglutide to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.

About 20 different Drug Products of Semaglutide are already registered in Bangladesh and freely available in market, the same can be verified from official website link.

https://dgdagov.info/index.php/registered-products/allopathic

Discussion of RB in 331st meeting: The Board was apprised that the firm has performed sameness evaluation data as per FDA criteria as below:

Primary Sequence & Physicochemical properties:

- Complete peptide sequence analysis by Mass spectrometry
- Molecular weight determination by Tris Tricine SDS-PAGE

Secondary Structure

- By circular Di-Chroism
- By Capillary Iso-electric focusing

Oligomeric states

- High molecular weight proteins by Size exclusion chromatography (SEC)

Biological activities

- Determination of specific activity by in-vitro Bioassay
- Protein content by ELISA

Decision: On the basis of documents/information/data along with sameness evaluation data as per FDA criteria and comparative testing with innovator product (Ozempic 2mg/1.5ml PFS of Novo Nordisk A/S), Registration Board approved the registration of Seglutide 2mg/1.5ml vial. The firm shall submit the non-clinical and clinical data of semaglutide finished product developed from same biological substance manufacturer i.e., Livzon.

Evaluation by DB&R:

The firm has submitted the following;

- Single dose toxicity studies of Seglutide injection 1.34mg/ml versus Ozempic (Reference) conducted in mice at M/s Dow University of Health Sciences, Karachi.
- A single dose, randomized, open label, parallel controlled pharmacokinetic Phase-I Clinical trial of Semaglutide Injection versus Ozempic in 64 healthy subjects.

Decision: The Registration Board endorsed its earlier decision of 331st Meeting.

Imported Human Biological (Heparin) approved in 334th RB meeting

98	**Name, address of Applicant / Importer**	**M/s We Care** Address: Flat B-6 Block 12 D 2nd Floor G-8 Markaz Islamabad Pakistan.
	Details of Drug Sale License of importer	**License No: DHO-ISB-930** **Address:** Flat B-6 Block 12 D 2nd Floor G-8 Markaz Islamabad Pakistan **Validity: 19-06-2025** **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s PT PRATAPA NIRMALA JL. INDUSTRI VI TANGERANG 15135-INDONESIA
	Name, address of manufacturer(s)	M/s PT PRATAPA NIRMALA JL. INDUSTRI VI TANGERANG 15135-INDONESIA
	Name of exporting country	Indonesia

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No.RG.01.05.32.321.05.22.3865) dated 17-05-2022 valid till 17-05-2024 issued by National Agency of Drug and Food control Jl. Percetakan Negara No. 23, JAKARTA-INDONESIA. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of 5's x 5mL vial in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized LOA dated 26-04-2022 and legalized distribution agreement dated 21-04-2022 (signed by both firms) valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5109 (R&I) dated 21-02-2023
	Details of fee submitted	Deposit Slip # 8167115543 of PKR. 150,000/- dated 22-02-2023
	The proposed proprietary name / brand name	**Inviclot Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Heparin Sodium……5000IU
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	-
	Proposed Pack size	5's x 5mL vial
	Proposed unit price	Not Provided
	Shelf Life	24 months
	Storage Conditions	Store Below 30°C
	The status in reference regulatory authorities	-
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow of manufacturing process, analytical procedures, justification of specification.
	Name, address of drug substance manufacturer	**Company:** Adeste Indústria de Produtos Animais LTD **Address:**Rua Paes Leme, 524, 6º andar Grupo 63 - CEP 054 24 904 Pinheiros – São Paulo – Brazil Phone: 55 11 30975544 Fax: 55 11 30975545
	Module-III Drug Substance:	Firm has submitted drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures, batch analysis and justification of specifications.

	Stability Studies of Drug Substance	Firm has provided stability studies of 3 batches of drug substance.
	Module-III Drug Product:	Firm has summarized data of drug product including its composition, manufacturing process, control of drug product, process verification, specifications, batch analysis, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods
	Container closure system of the drug product	Heparin Sodium 5000 units/mL is supplied as 5-mL volume injection, in a vial made of type I glass and packed in a box. Each container bears printed information concerning product characteristics (name, active ingredient, pharmaceutical form, strength) and batch characteristics (batch number and expiration date). The suitability of the primary packaging is confirmed by the Certificate of Quality from the vial manufacturer. Incompatibilities with primary packaging or excipients used were not observed; however, during the stability study there were not any particles leaked and the parameters tested remained within the requirements.
	Stability study data of drug product	Firm has submitted stability study data of 03 batches. The accelerated stability studies are conducted at 40 ± 2^0C/75%RH±5% for 6 months. The real time stability studies are conducted at 30 ± 2^oC/75%±5RH for 36 months for one batch. While at 30 ± 2^oC/60%±5RH for other two batches. Bacterial Endotoxin test and sterility test are performed at 0,6,12,24 months in real time stability studies while at 0 and 6 months in accelerated stability studies.
	Remarks of Evaluator	The firm has not performed testing as per official pharmacopeia.
	Decision of RB in 331st meeting	*Registration Board deferred the case for submission of specifications, analytical procedures and COAs as per official pharmacopoeia.*
	Decision of RB in 332nd meeting	*The case was discussed in 331st meeting of Registration Board. No response received from the firm. Case was deferred for clarification by the firm.*
	Remarks of Evaluator	The firm has submitted analytical methods and Certificate of analysis as per British Pharmacopoeia. However, the test of Zone electrophoresis has not been performed for Identification as mentioned in BP monograph.
	Decision of RB in 334th meeting	*On the basis of documents/information/data submitted by the applicant, Registration Board approved the product subject to submission of analytical method and certificate of analysis depicting Identification test by Zone electrophoresis as mentioned in BP monograph and subsequent compliance to current import policy for finished drugs.*
	Remarks of Evaluator	The firm has submitted a justification letter from manufacturer that they cannot perform identification test using electrophoresis because they don't have the electrophoresis instrument.
Decision: Registration Board approved the product subject to receipt of analytical method and certificate of analysis indicating Identification test by Zone electrophoresis as mentioned in BP monograph and fulfillment of current import policy.		

For information (Ratification) of the Registration Board:

Following product of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi was approved in 295th and then 330th meeting of Registration Board. The details are as below:

Sr. No.	Brand name and composition	Manufacturer and Market Authorization Holder	Packing, demanded price and shelf life	Decision of 295th & 330th RB meeting
99	Biofactor Streptokinase 15,00,000 Powder for infusion Each vial contains: Streptokinase...15,00,000 IU **New applied Brand Name:** Streptokinase Karma 15,00,000 Powder for infusion **(BP Specifications)**	**Manufacturer:** M/s Lyocontract GMBH Pulverwiese, Trift, Ilsenburg, D-38871, Germany. **Marketing Authorization Holder:** M/s Karma-Medica, GMBH Emil-Von-Behring Strasse 76, Marburg, D-35041, Germany.	1's Vial As per DPC 12 months (Store at 30^0C)	**M-295:** *Keeping in view the valid legalized CoPP indicating product availability in country of origin & approval of MHRA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.* **M-330:** *The product "Streptofactor" of M/s Hakimsons (Impex) Pvt Ltd. Karachi and the product "Biofactor Streptokinase" of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi, which was approved in 295th meeting of Registration Board, are having different Marketing Authorization Holders with different brand names and manufacturing sites. Thus, the Board decided to process registration of "Biofactor Streptokinase" of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi in the light of decision of 295th meeting of Registration Board.*

The firm has applied for Change of title and address of importer as per new DSL from "**M/s Lab Diagnostic System Pvt. Ltd., 111, Hali Road, Westridge 1, Rawalpindi"** to **"M/s Lab Diagnostic Systems (SMC) Pvt Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi" vide letter dated 24th May, 2024 and fee of Rs.7500/- is submitted under the head of pre-registration variation.**

The request of the firm for change of title and address of importer was acceded to by the Chairman Registration Board and the registration letter after incorporating above said change was issued accordingly.

The Chairman Registration Board and the Director Bio advised to place the case in the upcoming meeting of registration board for ratification and for clarification that the variations applied by the firms after approval of the product by the Registration Board but before issuance of the Registration letters will be considered as Pre-Registration variations.

Decision: The Board endorsed the above stated information and Decision.

CASES OF DD-IV (MS. ANAM SAEED)

Virtual Inspection Report of Manufacturer Abroad

Following product applied by M/s Pharmax Pakistan Pvt. Ltd., Karachi has been approved by Registration Board in its 331st meeting held on 31st October 2023 to 2nd November 2023;

Manufacturer	Brand Name & Composition

M/s NPO Petrovax Pharm, Limited Liability Company (NPO Petrovax Pharm, LLC), Address: 1 Sosnovaya St., Pokrov Village, Podolsk, Moscow Region, 142143, Russia.	**Grippol Quadrivalent** **Influenza quadrivalent inactivated subunit adjuvant vaccine, solution for Intramuscular and subcutaneous administration** Each dose contains (0.5 mL): Active ingredients: Influenza virus type A (H1N1) antigen with hemagglutinin…….5µg Influenza virus type A (H3N2) antigen with hemagglutinin…….5µg Influenza virus type B (Yamagata line) antigen with hemagglutinin…….5µg Influenza virus type B (Victoria line) antigen with hemagglutinin……..….5µg Polyoxidonium, active Pharmaceutical ingredient lyophilisate (expressed as Azoximer bromide) …….500µg

The Board has constituted following panel for GMP virtual inspection of manufacturing facility abroad (mentioned above);

i) Mr. Akbar Ali, Deputy Director QA&LT Division, DRAP.
ii) Ms. Anam Saeed, Deputy Director, BE&R Division, DRAP.

Accordingly, an inspection was carried out by inspection panel (mentioned above) dated 18-12-2023 and final remarks of the panel are as under: -

Recommendations of the panel:

Based on the virtual inspection **of M/s NPO PETROVAX PHARMA, LLC., RUSSIA** conducted, documents reviewed, interview of the management and technical person conducted, **panel of inspectors is of the view, <u>not to recommend Good Manufacturing Practices</u> for below product due to critical observations as below:**

Manufacturer	Brand Name & Composition
M/s NPO Petrovax Pharm, Limited Liability Company (NPO Petrovax Pharm, LLC), Address: 1 Sosnovaya St., Pokrov Village, Podolsk, Moscow Region, 142143, Russia.	**Grippol Quadrivalent** **Influenza quadrivalent inactivated subunit adjuvant vaccine, solution for Intramuscular and subcutaneous administration** Each dose contains (0.5 mL): Active ingredients: Influenza virus type A (H1N1) antigen with hemagglutinin…….5µg Influenza virus type A (H3N2) antigen with hemagglutinin…….5µg Influenza virus type B (Yamagata line) antigen with hemagglutinin…….5µg Influenza virus type B (Victoria line) antigen with hemagglutinin…….5µg Polyoxidonium, active Pharmaceutical ingredient lyophilisate (expressed as Azoximer bromide) ……..….500µg

Short Comings/ Observations:

- *It is pertinent to mention that complete dedication and self-contained facility for manufacturing of Viral vaccine manufacturing is not provided as Pneumococcal vaccine (Prevnar-13) is manufactured within same area used for manufacturing of Flu vaccine (viral vaccine) on same PFS machine. However, this building has common warehouse, personnel and material entrance, So the dedicated and self-contained facility as required is not provided which would result in potential hazard of cross contamination of General Injections with influenza vaccine.*

- *The building is not completely dedicated and self-contained regarding the manufacturing of biological product /Vaccine as required in section 5.2 of schedule B of Drugs (Licensing, Registration & advertising) rules 1976 as the biological manufacturing area shares common entrance into building, the CNC corridor leads to all areas of building including Pharmaceutical manufacturing area, i-e General ampoule and vial manufacturing area, solid dosage form, API manufacturing area. Facility also share common ware house for storage of Biological (vaccine) and non-biological Pharmaceutical raw materials.*

- *Firm intimated that they are not producing viral antigens instead they are procuring monovalent viral antigens harvest pool from another source outside of their facility, I-e M/s Adimmune Corporation, Tiawan, and reconstituting, filling and packing at this facility. European Pharmacopoeial monograph of influenza vaccine referees for choice of virus strain, as under and elaborates master seed till filling and release of vaccine as single process and also mentions choice of master virus seed, selection of substrate for viral propagation, harvesting, inhibition of viral activity and splitting and inhibition of virus antigen by appropriate agent. i-e Formaldehyde and purification /potentization of virus antigen.*

  CHOICE OF VACCINE STRAIN

  "The World Health Organization reviews the world epidemiological situation annually and if necessary recommends the strains that correspond to this epidemiological evidence. Such strains are used in accordance with the regulations in force in the signatory States of the Convention on the Elaboration of a European Pharmacopoeia. It is now common practice to use reassorted strains giving high yields of the appropriate surface antigens. The origin and passage history of virus strains shall be approved by the competent authority."
- *European Medicine Agency vide their Guidance Document No. Doc. Ref. EMEA/CHMP/VWP/263499/2006 for inactivated influenza vaccines prepared from viruses with the potential to cause a pandemic that have been isolated from:*

  • animals (e.g. avian or porcine strains) or

  • humans (i.e. strains of hemagglutinin (HA) subtypes other than H1 or H3) also mentioned the manufacturing as single process. However, the panel did not witness manufacturing of Monovalent viral antigen harvest pool as Active substance which remains outside the scope of this GMP inspection.
- *Firm intimated that they are outsourcing abnormal safety testing on animal models from outsource / third party firm. Firm also intimated that they are following Russian pharmacopoeia, however they were found not performing certain tests as per European Pharmacopoeia including formaldehyde residual contests, residual virus testing specifications are also different from EP. Firm acknowledged and submitted comparison of testing specifications of Russian and European pharmacopoeial, which is different.*

Product characteristics	**Method**	**Eligibility Criteria**	**Ccomparison of methodology and acceptance criteria**
Description	Visual SP RF	Colorless or yellowish slightly opalescent liquid.	Requirement of the SP-RF. This requirement is not included in the Ph. Eur.
Identification	Hemagglutination-inhibition test (HI-test) SP RF	Each subtype and type of antigen should be neutralized by homologic serum. The titer with heterologic serum should be lower than its own titer in not less than 4 times.	Requirement of the SP-RF. This requirement is not included in the Ph. Eur.
Clarity	Visual SP RF Ph. Eur. 2.2.1	The product should conform to the Reference Solution III.	There are no differences. Acceptance criteria and methods are the same
Color	Visual SP RF Ph. Eur. 2.2.1	Color intensity must not exceed that for Reference Y_5.	There are no differences. Acceptance criteria

			and methods are the same
Particulate contamination: visible particles	Visual SP RF Ph. Eur. 2.9.20	The product should correspond to the requirements.	There are no differences. Acceptance criteria and methods are the same
pH	SP RF, Ph. Eur. 2.2.3 potentiometry	7.0 to 7.6.	There are no differences. Acceptance criteria and methods are the same
Protein	Lowry protein assay SP RF Ph. Eur. 2.5.33	Less than 120 µg/0.5 ml excluding the quantitative hemagglutinin content.	There are no differences. Acceptance criteria and methods are the same
Extractable volume	SP RF Ph. Eur. 2.9.17	NLT nominal.	There are no differences. Acceptance criteria and methods are the same
Sterility	Membrane filtration or direct inoculation method SP RF Ph. Eur. 2.6.1	Must be sterile.	There are no differences. Acceptance criteria and methods are the same
Bacterial endotoxins	Gel clot test SP RF Ph. Eur. 2.6.14	Not more than 100 EU/mL	There are no differences. Acceptance criteria and methods are the same
Abnormal toxicity	SP RF Ph. Eur. 2.6.9	The product must be non-toxic.	The article 2.6.9 was removed from the Ph. Eur.
Specific safety	***SP Russian Pharmacopoeia Ph. Eur. 0869***	***Must not contain live influenza virus.***	***According to the Ph. Eur. procedure, the test is not valid unless at least 8 of 10 embryos survive after incubation. In SP-RF – 7 of 10***
Specific activity	***Single radial immunodiffusion assay (SRID) SP RF Ph. Eur. 0869, 2.7.1***	***The product must contain 5.0 to 7.2 µg of hemagglutinin of the influenza A virus subtypes A (H1N1), A (H_3N_2), and types B/Yamagata and B/Victoria per a dose of 0.5ml.***	***Differences between acceptance criteria: The Ph. Eur uses confidence limits and lack of overlap as an assessment of the suitability of a system. The confidence limits (P = 0.95) are not less than 80 per cent and not more than 125 per cent of the estimated***

			content. The lower confidence limit (P = 0.95) hemagglutinin antigen is not less than 80 per cent of the amount stated on the label for each strain. We work according to the SP-RF and for evaluation we use Delta values (distances between the starting points of the sample and the standard not more than 3 mm^2).
Polyoxidonium	Spectrophotometry Ph. Eur. 2.2.25	0.4 to 0.6 mg/0.5mL.	Petrovax in-house method
Immunogenicity	hemagglutination-inhibition test (HI-test) SP RF	The vaccine must meet the requirements.	Requirement of the SP-RF. This requirement is not included in the Ph. Eur.
Reactogenicity	SP RF	The vaccine must be areactogenic or low reactogenic	Requirement of the SP-RF. This requirement is not included in the Ph. Eur.
Ovalbumin	ELISA SP RF Ph. Eur., 2.7.1	Not more than 0.4 μg/0.5mL.	There are no differences. Acceptance criteria and methods are the same

Submitted for consideration of Board.

Decision: In light of recommendations given by the inspection panel, the Board decided to reject the registration application of Grippol Quadrivalent Vaccine manufactured by M/s NPO Petrovax Pharm, Limited Liability Company (NPO Petrovax Pharm, LLC), Russia.

CASES OF DD-II (DR. H.M JAWAD ALI)

- **Locally manufactured veterinary biological applied by M/s Hirra Pharmaceutical Laboratories Pvt. Ltd., Lahore.**

100.	Name of Importer & Address	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name Dosage Form & Strength	HIRRA ND FLU VAC
	Composition	Each dose of 0.3 ml contains: 1. Inactivated NDV containing not < 64HAU and EID_{50} not < 10^7/ml (Active Substance) ----------0.06ml 2. Inactivated AIV H9N2 containing not < 64HAU and EID50 not < 10^7/ml (Active Substance)---------- 0.06 ml
	Finished Product Specifications	European Pharmacopeia
	Pharmacological Group	Biological (Vaccine for veterinary/poultry use only)
	Shelf Life & Storage	12 months at 2-8 ^{0}C

	Type of Form+ Dy. No & Date of Application+ Fee	R&I. 18771. Form –5. Received via eapp (WQ6-69T-5ST6) on 03-06-2024. Rs. 30,000.00 *vide* Deposit Slip No. 2287765415. dated 31-05-2024.
	Demanded Price Demanded Pack Size	Decontrolled Bottle of 50 ml, 100 ml, 150 ml, 300 ml.
	Me too	GPVAC ND FLU 9. (Grand Pharma (Pvt) Ltd. ISB) Regn. #. 091881. (Strains are same but strength. is different)
	GMP status	New License DML # 000449 issued on 16-01-2024
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. Previously, the Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd., Karachi to submit registration applications on Form5/ Form 5-A/ Form 5D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of AJ Mirza Pharma Pvt Ltd., Karachi. The request of M/s Hirra Pharmaceutical Laboratories, Lahore is hereby submitted for the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. Decision of Authority's 178 meeting: The Authority, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for: - i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
	Remarks	• Form 5 is not provided; (no annexures except section approval) • Composition is not clear; • Finished Product Specifications are not provided.
	Decision: Approved. The firm will inform the strain.	
101.	Name of Importer & Address	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name Dosage Form Strength	HIRRA FLU VAC 5 Avian Influenza Virus (AlV) H5N8.

		"0.3 ml as *"Day-old vaccination is generally accomplished by giving 0.2 to 0.5 ml of vaccine subcutaneously)' under the skin at the back of the neck or intramuscularly in the leg".*
	Composition	Inactivated Al V H5N8 (EID50 not less than 108/ml) and Hemagglutinating units not < 128 HAU……..… 0.15ml
	Finished Product Specifications	Manufacturer's Specifications.
	Pharmacological Group	Biological (Vaccine for veterinary/poultry use only)
	Shelf Life & Storage	12 months at 2-8 ^{0}C
	Type of Form Dy. No & Date of Application Fee Submitted	R&I. 18784. Form –5. Received via eapp (XN4-GH5-S818) on 03-06-2024. Rs. 30,000.00 *vide* Deposit Slip No. 099484932. dated 30-05-2024
	Demanded Price	Decontrolled
	Demanded Pack Size	Bottle of 50 ml, 100 ml, 150 ml, 300 ml
	Me too status.	GPVAC FLU-5 (Grand Pharma (Pvt) Ltd. ISB)
	Deliberation of 178th Authority Meeting:	<u>Consideration of Application of Registrations Out of Queue</u>: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. Previously, the Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd., Karachi to submit registration applications on Form5/ Form 5-A/ Form 5D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of AJ Mirza Pharma Pvt Ltd., Karachi. The request of M/s Hirra Pharmaceutical Laboratories, Lahore is hereby submitted for the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. <u>Decision of Authority's 178 meeting:</u> The Authority, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for:- iii. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and iv. Grant of same registration numbers and brand names.

	Remarks	• Form 5 is not signed and stamped; • Composition is not clear; • Finished Product Specifications are not provided.
Decision: Approved. The firm will inform the strain		
102.	Name of Importer & Address	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name Dosage Form Strength	HIRRA ND VAC Newcastle Disease Virus (NDV) "*Newcastle disease (ND) is caused by virulent strains of avian paramyxovirus type I (APAIV-I) of the genus Avulavirus belonging to the family Paranzyxoviridae. There are ten serotypes of avian paramyxoviruses designated APMV-I to APMV-IO. ND virus (NDV) has been shown to be able to infect over 200 species of birds, but the severity of disease produced varies with both host and strain of virus.*"
	Composition	Inactivated Newcastle Disease Virus containing EID50 not less than 10^{70}/ml and HAU not less than 64 — 0.12 ml per dose
	Finished Product Specifications	Manufacturer's Specifications.
	Pharmacological Group	Biological (Vaccine for veterinary/poultry use only)
	Shelf Life & Storage	12 months at 2-8 ^{0}C
	Type of Form Dy. No & Date of Application Fee Submitted	R&I. 18773. Form –5. Received via eapp (GVQ-XTU-BSE7) on 03-06-2024. Rs. 30,000.00 *vide* Deposit Slip No. 4250677194. dated 31-05-2024
	Demanded Price Demanded Pack Size	Decontrolled Bottle of 50 ml, 100 ml, 150 ml, 300 ml.
	Me too status	• ORNIVAC ND Emulsion (M/s. SNAM Pharma, Lahore) Regn. #. 087884. (Strains are same but strength. is different)
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. Previously, the Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd., Karachi to submit registration applications on Form5/ Form 5-A/ Form 5D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of AJ Mirza Pharma Pvt Ltd., Karachi. The request of M/s Hirra Pharmaceutical Laboratories, Lahore is hereby submitted for the Authority regarding the consideration of submitted

		applications of registration of out of Queue with same registration numbers and brand names. Decision of Authority's 178 meeting: The Authority, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for: - i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and; ii. Grant of same registration numbers and brand names.
	Remarks	• Form 5 is not signed and stamped; • Composition is not clear; • Finished Product Specifications are not provided.
Decision: Approved. The firm will inform the strain		
103.	Name of Importer & Address	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name Dosage Form Strength	HIRRA FLU VAC PLUS Avian Influenza Viruses (AlVs) H5 & H9 "0.3 ml as *"Day-old vaccination is generally accomplished by giving 0.2 to 0.5 ml of vaccine subcutaneously)' under the skin at the back of the neck or intramuscularly in the leg".*
	Composition	Inactivated Al V F19N2 containing not < 64HAU and EID50 not < 10^7/ml — 0.075 ml per dose Inactivated Al V Id5N8 containing not < 64HAU and EID50 not < 10^7/mI — 0.075 ml per dose
	Finished Product Specifications	Manufacturer's Specifications.
	Pharmacological Group	Biological (Vaccine for veterinary/poultry use only)
	Shelf Life & Storage	12 months at 2-8 ^{0}C
	Type of Form Dy. No & Date of Application Fee Submitted	R&I. 18784. Form –5. Received via eapp (DB5-M35-NHD6) on 03-06-2024. Rs. 30,000.00 *vide* Deposit Slip No. 830965359109. dated 31-05-2024
	Demanded Price Demanded Pack Size	Decontrolled ▪ Bottle of 100ml 300m' and 500 ml
	Me too status.	1. GPVAC ND+FLU (Grand Pharma (Pvt) Ltd. ISB)
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. Previously, the Authority, keeping in view the decision of the Appellate

		Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd., Karachi to submit registration applications on Form5/ Form 5-A/ Form 5D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of AJ Mirza Pharma Pvt. Ltd., Karachi. The request of M/s Hirra Pharmaceutical Laboratories, Lahore is hereby submitted for the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. <u>Decision of Authority's 178 meeting:</u> The Authority, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for: - v. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and vi. Grant of same registration numbers and brand names.
	Remarks	• Form 5 is not signed and stamped; • Composition is not clear; • Finished Product Specifications are not provided.
Decision: Approved. The firm will ensure the biosafety measures to handle the seed material before inactivation.		
104.	Name of Importer & Address	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name Dosage Form Strength	Hirra FLU VAC-9 Avian Influenza Virus (AlV) H9N2 "There are three Influenza types A, B and C, only Influenza A is known to infect the birds. Vaccination against H9N2 Influenza A virus has been used extensively in Asia and Middle East. "
	Composition	Inactivated AIV H9N2{Containing EID50 not<10^6/ml and Hemagglutinating unit not < of 128 HAU}……..……..0.12ml/0.3ml dose
	Finished Product Specifications	Manufacturer's Specifications.
	Pharmacological Group	Biological (Vaccine for veterinary/poultry use only)
	Shelf Life & Storage	12 months at 2-8 ^{0}C
	Type of Form Dy. No & Date of Application Fee Submitted	R&I. 18781. Form –5. Received via eapp (5AZ-7TB-L47V) on 03-06-2024. Rs. 30,000.00 *vide* Deposit Slip No. 2353218001. dated 31-05-2024
	Demanded Price Demanded Pack Size	Decontrolled Bottle of 50 ml, 100 ml, 150 ml, 300 ml.
	Me too	GPVAC FLU H9. (Grand Pharma (Pvt) Ltd. ISB)
	Deliberation of 178th Authority Meeting:	<u>Consideration of Application of Registrations Out of Queue</u>: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the

		License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. Previously, the Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd., Karachi to submit registration applications on Form5/ Form 5-A/ Form 5D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of AJ Mirza Pharma Pvt Ltd., Karachi. The request of M/s Hirra Pharmaceutical Laboratories, Lahore is hereby submitted for the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. <u>Decision of Authority's 178 meeting:</u> The Authority, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for: - i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
	Remarks	• Form 5 is not signed and stamped; • Composition is not clear; • Finished Product Specifications are not provided.
• **Decision: Approved. The firm will inform the strain**		

<u>CASES OF DD-III (Ms. HALEEMA SHARIF)</u>

105.	**Name, address of Applicant / Importer**	**M/s Eastern Medical Care (Pvt) Ltd.**
	Details of the Drug Sale License of the importer	**Address:** 7A, Block N, Model Town, Lahore. **Validity: 17.10.2022** **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	M/s. Private Joint Stock Company, On the production of Insulin "INDAR". Address: 5, Zroshuvalna, Str. Kyiv, Ukraine
	Name, and address of the manufacturer(s)	M/s. Private Joint Stock Company, On the production of Insulin "INDAR". Address: 5, Zroshuvalna, Str. Kyiv, Ukraine
	Name of the exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized CoPP certificate (No.CPP/UA/24/20/7) and letter of authorization valid till December 20, 2027.

	Details of letter of authorization / sole agency agreement	Letter of Authorization valid till December 20, 2027.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 2409___25 Jan 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Protamin Sulphate** Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains Protamin Sulphate……..…..…….10mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antidote of Heparin
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	1's Vial (5ml)
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved in USFDA.(10mg/ml)
	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies.
	Name, address of drug substance manufacturer	**Manufacturer**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan **Responsibility**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan **Manufacturing**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan

		Testing, Subdividing, Labeling, Packaging, Storage and distribution: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for related to nomenclature, characterization, general properties, solubilities, physical form, manufacturers, specifications analytical procedures, batch analysis and justification of specification and reference standards.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -25ºC ± 2ºC & 60%RH±5%RH. The stability study data is till 60 months. The accelerated stability data is conducted at 40ºC ± 2ºC & 75%RH±5%RH. The stability study data is till 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, excipients, physical, chemical and biological properties, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/ verification of product	Firm has submitted analytical method from European Pharmacopoeia.
	Container closure system of the drug product	Medicinal product is filled in injection vial made of a transparent, colorless glass of 1 hydrolytic class (Type I), hermetically sealed under aseptic conditions with closure component-Flips for injection vials (combi seal), The Flip consists of a rubber liner, and aluminum crimp cap and a plastic lid of the type " Flip-Off".
	Stability study data of drug product, shelf life and storage conditions	Shelf Life 3 years below 25℃. Firm has submitted stability study data of 3 batches The real time stability studies are conducted at (30℃±2℃/65%RH±5%RH for 48 months for 10ml and 5ml vial accelerated stability study data is conducted at (40℃±2℃/75%RH±5%RH for 6 months for 10ml vials only.
	Module IV	Single dose toxicity studies are performed only
	Module V	Open label, comparative and parallel group study was carried on 86 patients: 43 patients in the main group and 43 patients in the reference group
Evaluation by PEC:		
Decision: Registration Board deferred the case for submission of following: • **Repeat dose toxicity & overdose toxicity studies of applied formulation.** • **Double blind Phase III clinical trials OR Evidence of guideline supporting Open label trials.** • **Clarification regarding pack size of applied formulation whether it is 5ml or 10ml.**		

Item No. IV. Additional Agenda

Agenda of Evaluator PEC-II

Case no. 01 Registration applications considered on priority against Export facilitation:

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e., one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma (Pvt) Limited. Plot No 13-14, Sector 15, Korangi industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Hilton Pharma (Pvt) Limited. Plot No 13-14, Sector 15, Korangi industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 7SP-N62-A98S dated November 29th, 2023
	Details of fee submitted	Rs.75000/- dated 2023-11-08
	The proposed proprietary name / brand name	**Bempix-EZE Tablets 180mg + 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic Acid .....180mg Ezetimibe 10mg
	Pharmacotherapeutic Group of (API)	Lipid modifying agents in combination with other drugs, ATC code: C10BA10
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Virata tablet of M/s CCL Pharmaceuticals

Evaluation by PEC^{II}:

Section #	Observations	Firm's response
3.2.P.2.2.1	Justification shall be submitted for use of surfactant in dissolution mediums for the performance of CDP studies for both Bempedoic acid and Ezetimibe	Bempedoic acid is water insoluble, addition of SLS (surfactant) in dissolution medium improve the solubility of poor water-soluble drugs. Furthermore, the dissolution test method is adopted from the US FDA (reference attached). The dissolution medium contains 0.45% SLS (surfactant), which was used for the CDP studies for both Bempedoic acid and Ezetimibe.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deputy Director PRV/EFD has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e., one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than 100,000 USD during the fiscal Year 2022-2023 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd A-115, S.I.T.E., Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd A-115, S.I.T.E., Super Highway, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: E88-EYP-1X79 dated February 6th, 2024
	Details of fee submitted	Rs.30,000/- dated 06-10-2023
	The proposed proprietary name / brand name	**Ticalor 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ticagrelor ……. 90mg
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors
	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Virata tablet of M/s CCL Pharmaceuticals
Evaluation by PEC[II]: BP monograph is available for the applied formulation.		
3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd A-115, S.I.T.E., Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd A-115, S.I.T.E., Super Highway, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 33H-JYE-4GMY dated December 15th, 2023
	Details of fee submitted	Rs.30,000/- dated 06-10-2023
	The proposed proprietary name / brand name	**Ticalor 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ticagrelor ……. 60mg
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors
	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Virata tablet of M/s CCL Pharmaceuticals
Evaluation by PEC[II]: BP monograph is available for the applied formulation.		

Decision: Registration Board approved the applications of Ticalor 90mg tablet and Ticalpr 60mg tablet with BP specifications. Firm shall submit fee of Rs. 7,500 for each strength for change of drug product specifications. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 02 Registration applications of New DML/New Section

- CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections including Liquid Ampoule (Steroid) section, in name of M/s Unison Chemical Works, Post Office Araian 15-Km Raiwind Road, Lahore – Pakistan

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Unison Chemical Works, Post Office Araian 15-Km Raiwind Road, Lahore – Pakistan**
	Name, address of Manufacturing site.	M/s Unison Chemical Works, Post Office Araian 15-Km Raiwind Road, Lahore – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: R87-MPJ-8G1M dated June 4th, 2024
	Details of fee submitted	Rs.30,000/- dated 24-0-2024
	The proposed proprietary name / brand name	**Unidex 4mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate ……4mg
	Pharmacotherapeutic Group of (API)	**Non- Synthetic Adrenocorticoid** **ATC Code: H02AB02**
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Decadron injection of M/s Searle
Evaluation by PEC[II]:		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

- M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore has been granted new section of "Tablet (Psychotropic section)" dated 14-10-2020.

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 5V4-HS5-YHQQ dated April 18th, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Chlordiazepoxide Tablet 10 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Chlordiazepoxide …….10mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Approved by US FDA; marketing status of the Reference product LIBRITABS of M/s Valeant Pharm Intl. has been declared as "Discontinued" in US FDA database of "Approved Drugs".
	For generic drugs (me-too status)	Liberan tablet of M/s Siza International
Evaluation by PEC[II]:		
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since submitted reference product has been declared as Discontinued by US FDA		
6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 767-X1D-ZZXY dated April 18th, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Cuzepam Tablet 2 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Lorazepam …….2mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Ativan tablet of M/s Pfizer
Evaluation by PEC[II]:		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**

	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 98Z-5EX-Q7HT dated May 2nd, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Diazepam 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Diazepam …….5mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Valium tablet of M/s Martin Dow
Evaluation by PEC[II]: Submit clarification regarding drug product specifications, whether pharmacopoeial or as per Innovator. • Responding to above observation firm has referred to the USP monograph of Diazepam tablets.		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: TP4-MT5-NHNJ dated April 23rd, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Diazepam 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Diazepam …….10mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Valium tablet of M/s Martin Dow
Evaluation by PEC[II]: Submit clarification regarding drug product specifications, whether pharmacopoeial or as per Innovator. • Responding to above observation firm has referred to the USP monograph of Diazepam tablets.		
Decision: Approved.		

• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 4PM-3LY-BQS8 dated April 18th, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Midaz Tablet 7 .5 mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Midazolam as Maleate ... 7.5 mg
	Pharmacotherapeutic Group of (API)	Benzodiazepines.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Dormicum 7.5 mg tablet of M/s Cheplapharm Arzneimittel GmbH, Approved by Netherland
	For generic drugs (me-too status)	Dormicum 7.5 mg tablet of M/s Martin Dow
Evaluation by PEC[II]:		
Decision: Approved. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 9N6-9HP-AW4M dated May 2nd, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Alzam 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Alprazolam …….1mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by US FDA

	For generic drugs (me-too status)	Xanax tablet of M/s Pfizer

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 1-04-2019.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Tablet (Psychotropic section)
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
Name and address of API manufacturer.	M/s Lake Chemicals Private Limited 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence & CDP studies have been submitted against Xanax 1mg tablet of M/s Pfizer
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

Evaluation by PEC[II]:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: MP1-SYP-PZUX dated April 23rd, 2024
	Details of fee submitted	Rs.30,000/- dated September 13th, 2023
	The proposed proprietary name / brand name	**Alzam 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Alprazolam …….0.5mg
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xanax tablet of M/s Pfizer

Evaluation by PEC[II]:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Case no. 03: Contract manufacturing applications applied on Form-5F

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals.** **Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18531 dated 24-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Prolide 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…2mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	As per Innovator's specifications
	The status in reference regulatory authorities	USFDA approved Motegrity® 2mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 2mg tablet Manufacturer: M/s Seraph (Reg. # 119162)
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
13.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18530 dated 24-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Prolide 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Reference to Finished product specifications	As per Innovator's specifications
	The status in reference regulatory authorities	USFDA approved Motegrity® 1mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 1mg tablet Manufacturer: M/s Seraph (Reg. # 119163)
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15388 dated 19-06-2023
	Details of fee submitted	Rs.75,000/- dated 22-06-2021
	The proposed proprietary name / brand name	**Nagson 100mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Hydrocortisone as Hydrocortisone Sodium Succinate…100mg
	Pharmacotherapeutic Group of (API)	CORTICOSTEROIDS FOR SYSTEMIC USE
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Cortizone injection of M/s Vision pharmaceuticals
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharma.** **8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 10573 dated 26-04-2023
	Details of fee submitted	Rs.75,000/- dated 26-07-2022
	The proposed proprietary name / brand name	**Biozole 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole…30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Dexova 30mg capsule of M/s Ameer & Adnan
Evaluation by PEC[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharma.** **8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 10574 dated 26-04-2023
	Details of fee submitted	Rs.75,000/- dated 26-07-2022
	The proposed proprietary name / brand name	**Biozole 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole…60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Dexova 60mg capsule of M/s Ameer & Adnan

Evaluation by PEC^{II}:
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 04 Routine registration applications applied on Form 5F

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 3141 dated 02-02-2023
	Details of fee submitted	Rs.30,000/- dated 27-12-2022
	The proposed proprietary name / brand name	**Empazin M 12.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin …… 12.5mg Metformin HCl …… 850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Synjardy tablet Approved by EMA
	For generic drugs (me-too status)	Diampa-M of M/s Getz pharma

Evaluation by PEC^{II}:

Section #	**Observations**	**Firm's response**
1.6.5	Valid GMP certificate/DML of drug substance manufacturers shall be submitted.	
3.2.S.4.4	COA of relevant batch of drug substances used for manufacturing of drug product trial batches, shall be submitted.	
3.2.P.2.2.1	Complete CDP study report including individual results for each unit in three dissolution mediums shall be submitted.	
3.2.P.5.1	Justification shall be submitted for proposing dissolution limit of "Within 60minutes" for Empagliflozin, since reference product literature approved by US FDA recommends dissolution limit of "Within 45 minutes" for Empagliflozin.	

	3.2.P.8.3	• Dissolution, limits mentioned n stability summary sheet for Metformin HCl are different form that submitted in drug product specifications. • Documents confirming procurement for drug substance shall be submitted. • Complete batch manufacturing record of drug product stability batches shall be submitted.	
Decision: Deferred for submission of reply to above cited shortcomings			
18.	**Name, address of Applicant / Marketing Authorization Holder**		**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.		/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission		Form 5F: Dy.No 37511 dated 22-12-2022
	Details of fee submitted		Rs.30,000/- dated 22-06-2022
	The proposed proprietary name / brand name		**Empozin XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Extended Release Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Pharmacotherapeutic Group of (API)		Anti-diabetic
	Reference to Finished product specifications		Innovator's specifications
	The status in reference regulatory authorities		Approved by US FDA
	For generic drugs (me-too status)		Xenglu-Met XR of M/s Hilton
19.	**Name, address of Applicant / Marketing Authorization Holder**		**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.		M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission		Form 5F: Dy.No 37511 dated 22-12-2022
	Details of fee submitted		Rs.30,000/- dated 22-06-2022
	The proposed proprietary name / brand name		**Empozin XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Extended Release Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Pharmacotherapeutic Group of (API)		Anti-diabetic
	Reference to Finished product specifications		Innovator's specifications

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR of M/s Hilton
20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 37512 dated 22-12-2022
	Details of fee submitted	Rs.30,000/- dated 22-06-2022
	The proposed proprietary name / brand name	**Empozin XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin Hcl…1000mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xenglu-Met XR of M/s Hilton

Evaluation by PEC[II]:

Section #	Observations	Firm's response
1.6.5	Valid GMP certificate/DML of drug substance manufacturers shall be submitted.	
3.2.S.4.4	COA of relevant batch of drug substances used for manufacturing of drug product trial batches, shall be submitted.	
3.2.P.2.2.1	Complete CDP study report including individual results for each unit in three dissolution mediums shall be submitted.	
3.2.P.5.1	Justification shall be submitted for proposing dissolution limit of "Within 60minutes" for Empagliflozin, since reference product literature approved by US FDA recommends dissolution limit of "Within 45 minutes" for Empagliflozin.	
3.2.P.8.3	• Dissolution, limits mentioned n stability summary sheet for Metformin HCl are different form that submitted in drug product specifications. • Documents confirming procurement for drug substance shall be submitted.	

		• Complete batch manufacturing record of drug product stability batches shall be submitted.	
Decision: Deferred for submission of reply to above cited shortcomings			

Case no. 05 Deferred cases:

21.	Name, address of Applicant / Marketing Authorization Holder	**M/s Albarakat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro**
	Name, address of Manufacturing site.	M/s Albarakat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection for grant of DML was conducted on 12.04.2023
	Evidence of approval of manufacturing facility	Liquid Ampoule (General), approval and granted by DRAP (Central Licensing Board) vide letter No. F. 2-7/2017-Lic, dated: 18-10-2023.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID QX6-QNW-BSE7 dated 01-03-2024
	Details of fee submitted	Rs.30,000/- dated 22-01-2024
	The proposed proprietary name / brand name	**Alfenac 75mg/3ml solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Diclofenac sodium ……75mg /3ml
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Ant rheumatic drug , non-steroids
	Pharmaceutical form of applied drug	Solution for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	3mlx10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Econac injection 75mg/3ml MHRA approved
	For generic drugs (me-too status)	Voren injection 75mg/3ml (Reg No 007737) By Asian continental
	Name and address of API manufacturer.	Aarti Drugs Limited, Plot No 109-D, Road No 29-Sion (East) Mumbai. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months DFS/301002, DFS/305060, DFS/309136
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Aarti Drugs Limited, Plot No 109-D, Road No 29-Sion (East) Mumbai. India		
API Lot No.	DFS/11040129		
Description of Pack (Container closure system)	Amber glass ampoule 3ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DF-TB-001	DF-TB-002	DF-TB-003
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
Manufacturing Date	05-2023	05-2023	05-2023
Date of initiation	18/05/2023	18/05/2023	18/05/2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Retention of License (w.e.f 01/01/2022 up to 31.12.2026) is provided dated 05.01.2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice No Exp/265/21-22 dated 22.04.2021 is provided wherein 1000kg diclofenac sodium (Batch No DFS/11040129 in the name of ISIS pharmaceuticals and chemical works. Approved by I&E DRAP dated 02.07.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

S.No	Observations	Reply	Remarks
1	**2.3.P.6** COA of primary / secondary reference standard including source and lot number to be provided	*CoA of working standard (diclofenac sodium) is provided which has been standardized against USP standard.*	Drug substance specification/ analytical method adopted was as per BP. However, USP reference standard was used.
2	**3.2.S.4** Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer	Provided under module 3 section 3.2.S.4.3	Analytical method verification study of Drug substance performed by Drug substance manufacturer instead of drug product manufacturer.
3	**3.2.P.2** Provide details of container closure system (Glass ampoule) such as glass type and suitability testing/Quality testing (as per relevant pharmacopeia) to be submitted	USP type I glass ampoule	Method of quality testing (as per USP) has been provided instead of performance report/results.
4	**3.2.P.2.2.1** Provide Pharmaceutical equivalence study and details of comparator/Reference product such as Exp. Date, Batch no. etc against which Pharmaceutical equivalence study was performed.	Pharmaceutical equivalence study performed against Voren injection by Asian continental (Batch No S2232, Exp date 10/2022)	

		Parameters compared were appearance, Ph and assay.	
5	**3.2.P.5:** Finished product specification mentioned on Form5F as USP while applied formulation is not found in any official monograph. Clarify applied finished product specification.	There is a typographic error in Form5F, the specification of mentioned product is **Albarakat specification**.	Data to be submitted as per 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023 Moreover fee (Rs 7500/-) is required for correction of finished product specification mentioned in Form5F.
6	**3.2.P.8** Provide loan agreement for borrowing API from M/s ISIS pharmaceuticals and chemical works, Karachi	Loan agreement for borrowing API (250g) from M/s ISIS pharmaceuticals and chemical works, Karachi is provided dated 02.05.2023	

Decision of 335th meeting: Deferred for following shortcomings:

a) Drug substance specification/ analytical method adopted was as per BP whereas USP reference standard was used.
b) Analytical method verification study of Drug Substance performed by Drug Product manufacturer is required.
c) Results of quality testing of USP type I glass ampoule (as per USP) to be submitted.
d) Since firm adopted finished product specification as manufacturer's specification hence needs to fulfil the criteria as laid down in 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023 and submit data accordingly.

Firm's response: Firm has replied as under:

- We standardized the working standard against the reference standard. We follow the BP method.
- Firm has submitted analytical method verification studies of drug substance.
- COA of Glass ampoule.
- Analytical method validation report of the drug product Assay method.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 06: Registration applications of Finished Drug Import

22.	Name and address of Applicant	M/s Revive Healthcare. Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Revive Healthcare. Address: Office 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore. Validity: 21st May, 2027 Status: License to sell drugs as a distributor (Form No.11)
	Name and address of manufacturer	M/s Emcure Pharmaceuticals Limited, Plot No. P1 & P2 I.T.B.T Park, Phase II, M.I.D.C. Hinjawadi Pune 411057 Maharashtra State, India.
	Name and address of marketing authorization holder	M/s Emcure Pharmaceuticals Limited, Plot No. P1 & P2 I.T.B.T Park, Phase II, M.I.D.C. Hinjawadi Pune 411057 Maharashtra State, India.
	Name of exporting country	India.
	Type of Form	Form-5F
	Diary No. & Date of R& I	Dy.No 23824 dated 31-08-2021
	Fee including differential fee	Rs.50,000/- dated 09-10-2020
	Brand Name +Dosage Form + Strength	**Inbec Tablet**
	Composition	Each Film Coated Tablet Contains: Abacavir as Sulphate…600mg Dolutegravir as Sodium…50mg Lamivudine…300mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Antivirals for treatment of HIV infections, combinations.
	Shelf life	24 months
	Demanded Price	As per SRO.
	Pack size	As per SRo
	International availability	USFDA approved.
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	**Letter of authorization: - (Copy submitted)** Firm has submitted notarized authorization letter from M/s Emcure Pharmaceuticals Limited, wherein they have authorized M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore for import, market, distribution and sale of the 08 products namely; Atazor-R Tablets, Tavin-EM Tablets, Instgra Tablets, Viropil Tablets, Spegra Tablets, Vonavir tablets, Inbec tablets and Vonday tablets. **Certificate of Pharmaceutical Product (Copy submitted).** Certificate No: COPP/CERT/PD/122638/2023/11/43793/212434 Certifying Authority: Food & Drug Administration, M.S. Bandra-Kurla complex, Bandra (E), Mumbai-400 051 Maharashtra, India. The certificate conforms to the format recommended by the WHO.

		Validity: 28-11-2024. Certificate also confirms that this product is also actually on the market in the exporting country along with GMP status through periodic inspection once a year

Reply by the firm:

Shortcomings	Reply
I- Submit differential fee for the registration of applied product since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021. **II-** Analytical Method verification studies by the Drug Product manufacturer required for both Abacavir sulfate & Lamivudine **III-** Provide the results of analysis of relevant batch of Abacavir sulfate and Lamivudine performed by drug product manufacturer used during development and stability studies along with certificate of analysis **IV-** Justify addition of surfactant in performance of comparative dissolution profile **V-** Justification is required for not submitting the stability data till claimed shelf life	**I-** Differential fee Rs. 25000/- has been submitted by the firm vide deposit slip# 9683875435 **II-** Analytical method verification data for both APIs (Abacavir sulfate & Lamivudine) provided by the firm **III**- COAs of both APIs (Abacavir sulfate & Lamivudine) from drug substance manufacturer and respective analysis reports by drug product manufacturer provided by the firm **IV-** Firm has provided the clarification from the product manufacturer that "FDA recommended dissolution method was adopted for Abacavir 600mg, Dolutegravir 50 mg and Lamivudine 300 mg Tablets. The dissolution method recommended by the FDA is "900 mL of 0.01M Sodium Phosphate buffer pH 6.8 containing 0.5% w/v Sodium lauryl sulfate using apparatus: USP type-II (Paddle) at 85 rpm". Dolutegravir Sodium API having low solubility and to achieve drug release in FDA recommended dissolution media; addition of surfactant in the performance of comparative dissolution study in release media is required. Firm also provided USFDA drug database link for verification of dissolution method adopted by the manufacturer. **V** Stability data till complete shelf life provided by the firm till 48 months for the long term and 6 months for accelerated.

Decision: Approved as per policy of Inspection of manufacturer abroad.

Agenda of Evaluator PEC-III

Applications of Anticancer products priority as per the decision of 257th meeting of RB.

23.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran

	Name, address of manufacturer(s)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: Z2Z-L7S-1LLW: 18-04-2024
	Details of fee submitted	PKR 300,000/-: 25-03-2024
	The proposed proprietary name / brand name	**Ibract 75 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Palbociclib.....75mg
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-house
	Proposed Pack size	Ibract ® 75 mg is available in boxes of 3 blisters (Alu-Alu), each one containing 7 capsules along with the package leaflet.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibrance Capsule by Pfizer (**USFDA** Approved)
	For generic drugs (me-too status)	Ibrance capsule by M/s Pfizer Karachi.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of legalized CoPP (No. 665/74216) dated 03-12-2023, issued by Division of Pharmaceutical and Narcotic affairs of Ministry of Health Food and Drug Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted scanned copy of Dstribution Certificate Acetro Middle East and Lab Diagnostic Systems (SMC-PVT) Ltd dated 15-01-2024.

Evaluation by PEC[3]:

Sr. No	Observations communicated	Response by the firm
1.	Submit stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition, since the submitted data is only for 1 batch.	

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

Registration Board further decided that registration letter will be issued after submission of following:

- **Original, Valid, Legalized CoPP to I&V Section.**
- **Valid, notarized / legalized letter of authorization.**
- **Stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition**

	○ **Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
24.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran
	Name, address of manufacturer(s)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: GDJ-YLR-7YS1: 18-04-2024
	Details of fee submitted	PKR 300,000/-: 25-03-2024
	The proposed proprietary name / brand name	**Ibract 100 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Palbociclib.....100mg
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-house
	Proposed Pack size	Ibract ® 100mg is available in boxes of 3 blisters (Alu-Alu), each one containing 7 capsules along with the package leaflet.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibrance Capsule by Pfizer (**USFDA** Approved)
	For generic drugs (me-too status)	Ibrance capsule by M/s Pfizer Karachi.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of legalized CoPP (No. 665/74218) dated 03-12-2023, issued by Division of Pharmaceutical and Narcotic affairs of Ministry of Health Food and Drug Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted scanned copy of Dstribution Certificate Acetro Middle East and Lab Diagnostic Systems (SMC-PVT) Ltd dated 15-01-2024.

Evaluation by PEC[3]:

Sr. No	Observations communicated	Response by the firm
1.	Submit stability study data of 3 batches of drug product till claimed	

	shelf life as per zone IV-A condition, since the submitted data is only for 1 batch for 6 months only.	

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. The registration letter will be issued after submission of following:

- **Original, Valid, CoPP.**
- **Valid, notarized letter of authorization.**
- **Stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition**
- **Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

25.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran
	Name, address of manufacturer(s)	Actero Middle East No.8th Golestan Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: U6Q-7NM-G6J6: 22-04-2024
	Details of fee submitted	PKR 300,000/-: 22-03-2024
	The proposed proprietary name / brand name	**Ibract 125 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Palbociclib.....125mg
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-house
	Proposed Pack size	Ibract ® 125 mg is available in boxes of 3 blisters (Alu-Alu), each one containing 7 capsules along with the package leaflet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibrance Capsule by Pfizer (**USFDA** Approved)
	For generic drugs (me-too status)	Ibrance capsule by M/s Pfizer Karachi.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of legalized CoPP (No. 665/74217) dated 03-12-2023, issued by Division of Pharmaceutical and Narcotic affairs of Ministry of Health Food and Drug Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.

	Details of letter of authorization / sole agency agreement	Firm has submitted scanned copy of Dstribution Certificate Acetro Middle East and Lab Diagnostic Systems (SMC-PVT) Ltd dated 15-01-2024.

Evaluation by PEC[3]:

Sr. No	Observations communicated	Response by the firm
1.	Submit stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition, since the submitted data is only for 1 batch for 6 months only.	

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

The registration letter will be issued after submission of following:

- **Original, Valid, CoPP to I&V Section.**
- **Valid, notarized letter of authorization.**
- **Stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition**
- **Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

26.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Zuvius Lifesciences Pvt. Ltd., At Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi Distt Solan, Himachal Pradesh, India.
	Name, address of manufacturer(s)	Zuvius Lifesciences Pvt. Ltd., At Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi Distt Solan, Himachal Pradesh, India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 846-QXW-ST36: 19-04-2024
	Details of fee submitted	PKR 300,000/-: 26-02-2024
	The proposed proprietary name / brand name	**Zolon-50 Injection 50mg/25ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Oxaliplatin 2mg
	Pharmacotherapeutic Group of (API)	Platinum containing antineoplastic agents
	Reference to Finished product specifications	USP
	Proposed Pack size	1 vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed.

		Available in USFDA as 50mg, 100mg and 200mg however its concentration is 5mg/ml. 50mg/10ml, 100mg/20ml and 200mg/40ml
	For generic drugs (me-too status)	Oxol 50mg/25ml Injection by M/s Helix Pharma (Pvt)., Ltd. (Reg # 072516)
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of legalized CoPP (No. 104/19/23-21) dated 27-10-2023, valid till 09-01-2025 issued by State drug Controller, Controlling cum Licensing authority H.P Baddi Dist Solan India. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted scanned copy of Letter of authorization between Zuvius Lifesciences Pvt Ltd and Lab Diagnostic Systems (SMC-PVT) Ltd dated 25-08-2023.

Evaluation by PEC[3]:

Sr. No	Observations communicated	Response by the firm
1.	Evidence of approval of applied formulation as 2mg/ml oxaliplatin concentration (i.e. 50mg/25ml), since the product approved by USFDA / MHRA etc contains 5mg/ml oxaliplatin (i.e. 50mg/10ml)	
2.	Submit stability study data of 3 batches of drug product as per zone IV-A condition, since the submitted real time stability study data is as per zone-II	

Proceedings: Registration Board was apprised that the applied formulation contains oxaliplatin 2mg/ml (i.e. 50mg/25ml), while the product approved by reference regulatory authorities (RRA) contains oxaliplatin 5mg/ml (i.e. 50mg/10ml)

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Registration Board further decided that registration letter will be issued after submission of following:

- **Original, Valid, Legalized CoPP to I&V Section.**
- **Valid, notarized / legalized letter of authorization.**
- **Stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition.**

27.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Zuvius Lifesciences Pvt. Ltd., At Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi Distt Solan, Himachal Pradesh, India.
	Name, address of manufacturer(s)	Zuvius Lifesciences Pvt. Ltd., At Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi Distt Solan, Himachal Pradesh, India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: EPS-WX7-5Z8W: 18-03-2024
	Details of fee submitted	PKR 300,000/-: 27-02-2024
	The proposed proprietary name / brand name	**Zolon-100 Injection 100mg/50ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Oxaliplatin 2mg
	Pharmacotherapeutic Group of (API)	Platinum containing antineoplastic agents
	Reference to Finished product specifications	USP
	Proposed Pack size	1 vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed. Available in USFDA as 50mg, 100mg and 200mg however its concentration is 5mg/ml. 50mg/10ml, 100mg/20ml and 200mg/40ml
	For generic drugs (me-too status)	Oxol 50mg/25ml Injection by M/s Helix Pharma (Pvt)., Ltd. (Reg # 072516)
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted scanned copy of legalized CoPP (No. 104/19/23-22) dated 27-10-2023, valid till 09-01-2025 issued by State drug Controller, Controlling cum Licensing authority H.P Baddi Dist Solan India. The certificate confirms the free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted scanned copy of Letter of authorization between Zuvius Lifesciences Pvt Ltd and Lab Diagnostic Systems (SMC-PVT) Ltd dated 25-08-2023.

Evaluation by PEC[3]:

Sr. No	Observations communicated	Response by the firm
1.	Evidence of approval of applied formulation as 2mg/ml oxaliplatin concentration (i.e. 100mg/50ml), since the product approved by USFDA / MHRA etc contains 5mg/ml oxaliplatin (i.e. 100mg/20ml)	

Proceedings: Registration Board was apprised that the applied formulation contains oxaliplatin 2mg/ml (i.e. 100mg/50ml), while the product approved by reference regulatory authorities (RRA) contains oxaliplatin 5mg/ml (i.e. 100mg/20ml)

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Registration Board further decided that registration letter will be issued after submission of following:

- **Original, Valid, Legalized CoPP to I&V Section.**
- **Valid, notarized / legalized letter of authorization.**
- **Stability study data of 3 batches of drug product till claimed shelf life as per zone IV-A condition.**

Registration application of WHO Prequalified Product:

M/s Pharmevo (Pvt) Ltd Karachi has submitted that recently their product **Zinc (sulfate) Syrup 10mg/5ml** has been prequalified by the WHO. Details of pre-qualification are as follows:

S. No.	WHO Reference Number	INN, Dosage Form and Strength	Date of Prequalification
1	DI010	Zinc (sulfate) Syrup 10mg/5ml	12th Jul 2023

The firm has submitted same application for grant of registration for local manufacturing on Form 5F vide Dy No: 27948: 01-12-2023 and prequalified drug has already been registered by DRAP with export purposes on June 18th, 201. In the light of aforesaid submission, the firm has requested to consider local manufacturing application on priority for consideration by the Board. Accordingly request of the firm along with application is placed bore the Board for its consideration:

28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy No: 27948: 01-12-2023
	Details of fee submitted	PKR 30,000/- : 24-07-2023
	The proposed proprietary name / brand name	**ZI-AD 10mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Zinc sulphate monohydrate eq to elemental zinc……10mg
	Pharmacotherapeutic Group of (API)	Mineral supplement
	Reference to Finished product specifications	USP / EP
	The status in reference regulatory authorities	**WHO PQ** Formulation
	For generic drugs (me-too status)	Zincasa syrup by Macter
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[3] :

The applied product is WHO pre-qualified with following details:
WHO Product ID: DI010
Status: Prequalified
INN, dosage form and strength: Zinc (sulfate) Syrup 10mg/5ml
Date of prequalification: 12 Jul, 2023
Basis of listing: Prequalification - Full
Therapeutic area: Diarrhoea
Type: Finished Pharmaceutical Product
Dosage form: Syrup
Applicant organization: PharmEvo (Pvt) Ltd. A-29, North Western Industrial Zone, Port Qasim Karachi, 75020 Pakistan

Decision: The Board keeping in view WHO prequalification status of the applied product, decided to approve the product.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration application of Zinc-ORS Combo Pack as per WHO essential model list

Registration Board in its 293rd meeting decided as under:
"**Registration Board advised to process any application of the referred formulation of "Zinc and ORS as combi-pack" against the reference of WHO Model list of Essential Medicines (EML).**

Accordingly, following application is submitted in the light of above decision for consideration of Registration Board.

29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim Karachi.**
	Name, address of Manufacturing site.	**Zinc Sulfate Dispersible Tablet:** M/s PharmEvo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim Karachi. **ORS Sachet**: Indus Pharma (Pvt.) Ltd Plot no. 26-27 and 63-67, Sector 27, Korangi Industrial Area, Karachi-74900, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: UD5-B65-GVME: 22-02-2024
	Details of fee submitted	PKR 75,000/- : 11-09-2023
	The proposed proprietary name / brand name	**ORS-Zi Copack**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Combo Pack contains: Oral Rehydration Salt (ORS) Sachet + Zinc Sulphate Dispersible Tablets **Each Sachet contains:** Sodium Chloride…….……2.60g Trisodium Citrate Dihydrate……2.90g Potassium Chloride……...1.50g Glucose Anhydrous…….13.50g **Each Dispersible Tablet contains**: Zinc Sulphate Monohydrate eq. to Elemental Zinc ……. 20mg
	Pharmacotherapeutic Group of (API)	Mineral supplement with rehydration salt
	Reference to Finished product specifications	Tablet: USP / Ph Int Sachet: BP
	The status in reference regulatory authorities	Firm has submitted copy of minutes of 293rd meeting of Registration Board wherein the Board has made this decision "Registration Board advised to process any application of the referred formulation of "Zinc and ORS as combi-pack"

		against the reference of WHO Model list of Essential Medicines (EML). Available in WHO EML
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[3] :

ORS will be manufactured as contract manufacturing by Indus Pharma (Pvt) Ltd., having a valid DML No. 000124 situated at Plots No.26, 27, 63, 64, 65, 66 & 67, Sector-27, Korangi Industrial Area, Karachi-74900, Pakistan.
Moreover, final packaging of ORS-Zi Co-pack will be done at PharmEvo (Pvt.) Ltd. having a valid DML no. 000504.

The Zinc Dispersible Tablet of M/s Pharmevo is WHO pre-qualified with following details:
WHO Product ID: DI009
Status: Prequalified
INN, dosage form and strength: Zinc (sulfate) Tablet, Dispersible 20mg
Date of prequalification: 12 Jul, 2023
Basis of listing: Prequalification - Full
Therapeutic area: Diarrhoea
Type: Finished Pharmaceutical Product
Dosage form: Tablet, Dispersible
Applicant organization: PharmEvo (Pvt) Ltd. A-29, North Western Industrial Zone, Port Qasim Karachi, 75020 Pakistan

Decision: The Board keeping in view WHO prequalification status of the Zinc Dispersible Tablet of M/s Pharmevo and its decision of 293rd meeting regarding "Zinc and ORS as combi-pack" against the reference of WHO Model list of Essential Medicines, decided to approve the product.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Priority as per 157 meeting of Authority dated 20-01-2023 for GMP from PIC/s member NRAs.

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dynatis Pakistan Pvt. Ltd. Plot 710, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Dynatis Pakistan Pvt. Ltd. Plot 710, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 5P4-LQZ-7AXY: 18-03-2024
	Details of fee submitted	PKR 30,000/- : 04-01-2024
	The proposed proprietary name / brand name	**BACTCID Tablet 250mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Ciprofloxacin hydrochloride equivalent to Ciprofloxacin……..250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Novidat Tablet by Sami
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dynatis Pakistan Pvt. Ltd. Plot 710, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Dynatis Pakistan Pvt. Ltd. Plot 710, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: Z3V-B44-JPAQ: 18-03-2024
	Details of fee submitted	PKR 30,000/- : 04-01-2024
	The proposed proprietary name / brand name	**BACTCID Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Ciprofloxacin hydrochloride equivalent to Ciprofloxacin……..500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Novidat Tablet by Sami
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

New Section / New License

32.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cure Laboratories (Pvt.) Ltd Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt.) Ltd Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: JQL-DTZ-5W3Y: 16-05-2024
	Details of fee submitted	PKR 30,000/- : 20-02-2024
	The proposed proprietary name / brand name	**MALRID Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains Artemether.....80mg Lumefantrine.....480mg
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	Ph Int
	The status in reference regulatory authorities	**WHO PQ Formulation**
	For generic drugs (me-too status)	Arceva 80/480mg Tablets (Sami pharmaceuticals).
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cure Laboratories (Pvt.) Ltd Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt.) Ltd Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: WRZ-1YQ-3E8G: 22-05-2024
	Details of fee submitted	PKR 30,000/- : 20-02-2024
	The proposed proprietary name / brand name	**CURLID Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid.....400mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Nezkil Tablet by Continental
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

34.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Med Asia Pharmaceuticals (Pvt) Ltd Plot No. 7, Nowshera Industrial Estate (SIZ) Risalpur**
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Ltd Plot No. 7, Nowshera Industrial Estate (SIZ) Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: RHM-QZE-YPE7: 29-04-2024
	Details of fee submitted	PKR 30,000/- : 12-12-2023
	The proposed proprietary name / brand name	**DXL 60mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin capsule contains Dexlansoprazole as dual delayed release pellets 60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit evidence of purchase of API	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit evidence of purchase of API before issuance of Registration letter.**

35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: BU7-THH-W3LX: 09-05-2024
	Details of fee submitted	PKR 30,000/- : 12-12-2023
	The proposed proprietary name / brand name	**JECTSOL-10 Infusion (500ml)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Dextrose anhydrous……10g
	Pharmacotherapeutic Group of (API)	Anti hypoglycemic
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Medisol 10% w/v Infusion by Medipak
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 5VQ-1RB-W3MV: 15-05-2024
	Details of fee submitted	PKR 30,000/- : 12-12-2023
	The proposed proprietary name / brand name	**JECTSOL-10 Infusion (1000ml)**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Dextrose anhydrous……10g
	Pharmacotherapeutic Group of (API)	Anti hypoglycemic
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Medisol 10% w/v Infusion by Medipak
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
37.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: E95-LSZ-BL22: 30-05-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL-PEADS Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.18g Dextrose Anhydrous……4.0g
	Pharmacotherapeutic Group of (API)	Anti hypoglycemic/ Electrolytes
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Sodium Chloride 0.18% and Glucose 4 % Solution **HPRA** Ireland Approved
	For generic drugs (me-too status)	UNISOL-PEADS INFUSION of UNISA
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Firm has applied for the formulation as per RRA reference, however all me-too approved with slightly different label claim. The difference is tabulated below:		

Formulation approved by RRA	**Locally registered product**
Each 1000ml contains: Sodium chloride…….1.8g	Each 100ml contains: Sodium chloride…….0.18gm

Glucose monohydrate……44.0g Eq to glucose anhydrous……40.0g	Dextrose anhydrous…….4.30gm

Decision: Registration after thorough deliberation and keeping in view the already approved products decided to approve the product with following label claim:

Each 100ml contains:

Sodium chloride…….0.18gm

Dextrose anhydrous…….4.30gm

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

38.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 883-G1V-E3VV: 21-05-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL-PEADS Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.18g Dextrose Anhydrous……4.0g
	Pharmacotherapeutic Group of (API)	Anti hypoglycemic/ Electrolytes
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Sodium Chloride 0.18% and Glucose 4 % Solution **HPRA** Ireland Approved
	For generic drugs (me-too status)	UNISOL-PEADS INFUSION of UNISA
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO

Evaluation by PEC[3] :

Firm has applied for the formulation as per RRA reference, however all me-too approved with slightly different label claim. The difference is tabulated below:

Formulation approved by RRA	**Locally registered product**
Each 1000ml contains: Sodium chloride…….1.8g Glucose monohydrate……44.0g Eq to glucose anhydrous……40.0g	Each 1000ml contains: Sodium chloride…….1.8gm Dextrose anhydrous…….43.0gm

Decision: Registration after thorough deliberation and keeping in view the already approved products decided to approve the product with following label claim:

Each 100ml contains:

Sodium chloride…….0.18gm
Dextrose anhydrous…….4.30gm

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

39.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuitcal Plot # 210, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. ANH-R19-T4RH: 03-06-2024
	Details of fee submitted	PKR 75,000/- : 20-05-2024
	The proposed proprietary name / brand name	**RESTON 8mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron hydrochloride dihydrate eq. to ondansetron……8mg
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit 6 months stability study data	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 6th month stability study data.**

Export Facilitation

40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt). Ltd. Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt). Ltd. Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: NRV-1Y1-WX3U: 12-12-2023
	Details of fee submitted	PKR 30,000/- : 27-11-2023
	The proposed proprietary name / brand name	**COLIMETHATE 4.5 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium ..... 4.5MIU equivalent to 150mg Colistin base activity approximately
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Coliate 4.5MIU injection by English Pharma
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC[3] :		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Agenda of Evaluator PEC-IV

d. Export facilitation

DD (PRV/EFD) vide letter No. F.1-6/2019-PR-II(EFD). dated 29-05-2024 has informed that The M/s Bio-Labs(Pvt).Ltd has achieved benchmark of USD 672,699 during fiscal year 2022-2023 and requested for priority consideration of following molecule the (1 molecule) 01 products:.		
41.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs(Pvt).Ltd Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan
	Name, address of Manufacturing site.	Bio-Labs(Pvt).Ltd Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID. Y7B-T8U-B3HH: 19-3-2024
	Details of fee submitted	PKR 30,000/- : De[posit Slip # 5325572922
	The proposed proprietary name / brand name	**Vemtix injection 4mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains; Ondansetron (as Hydrochloride Dihydrate) …….4mg
	Pharmacotherapeutic Group of (API)	Anti-emetic

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Zofran Injection 2mg/ml of Novartis Pharmaceuticals UK Limited, of MHRA approved.
	For generic drugs (me-too status)	Zofran Injection 8mg/4ml of M/s Novartis
Evaluation by PEC (No[4]):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

e. Deferred cases

42.	Name and address of manufacturer / Applicant	Glitz Pharma, Plot No 265, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Memanta 10mg/5ml Syrup
	Composition	Each 5ml contains:- Memantine HCl ……..10mg
	Diary No. Date of R& I & fee	Dy. No.1413 , R&I Dated 31-10-14 , Rs: 20,000/-
	Pharmacological Group	Anti-Parkinson
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml,90ml,120ml,240ml,300ml, Amber glass bottle, As per policy of MOH
	Approval status of product in Reference Regulatory Authorities	Memantine Sandoz 10mg/ml (MHRA)
	Me-too status	Zexa by English Pharm, Lahore (R. No. 071544)
	GMP status	GMP inspection Date: 29-11-2016, GMP status is not clear.
	Remarks of the Evaluator	I. The evidence provided for liquid syrup section is of 2005. II. 251st meeting commitment not provided by the firm. III. Incorrect pharmacological group provided by firm. IV. Incorrect International availability provided by firm.
	Decision of 270th: Deferred for the following reasons: Confirmation of approval status by reference regulatory authorities. Clarification of pharmacological group. Submission of commitments as per decision of Registration board taken in its 251st meeting. Clarification of pharmacopoeia reference.	
	Evaluation: The firm has submitted pharmacological group: NDMA receptor antagonists or used to treat dementia. USP specification. International reference could not be confirmed. Commitments did not submit GMP certificate valid till 2023.	
	Previous Decision (M-320): Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm submitted RRA reference of : Memantine Crescent 10 mg/ml oral solution by Crescent Pharma Limited, of MHRA approved.	
	Decision: Approved.	
43.	Name and address of manufacturer / Applicant	M/s Venus Pharma 23 km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Predol Injection 5mg
	Composition	Each ml contains:- Haloperidol…..5mg

	Diary No. Date of R& I & fee	Dy No.17645, 11-05-2018, Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Halotec Plain Injection of Pharmatec Karachi
	GMP status	GMP Certificate issued on 27-08-2018
	Remarks of the Evaluator	
	Decision of 286th meeting: Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. Evaluation by PEC: Applied formulation does not fall in the category of controlled drugs. Decision of 288th meeting: Registration Board decided to defer the case for the following reasons: For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs. For consideration of case on its turn. Submission by the firm: The firm has submitted GMP certificate No. 353/2019-DRAP(AD-1915187-536) dated 28/11/2019 issued on the basis of inspection conducted on 05/09/2019. The firm has submitted inspection report for renewal of DML dated 07/04/2017. As per report, Liquid injectable (ampoule) section is approved.	
	Previous Decision (M-312): Deferred for confirmation of approved manufacturing facility for Liquid Injectable (ampoule) section.	
	Firm submitted copy of renewal of Drug manufacturing License in which Liquid Ampoule Section (General) section mentioned. Firm Submitted cGMP certificate on the basis of evaluation conducted on 22-08-2023 & 14-09-2023 in which Liquid Injectable (Vial & Ampoule) section mentioned.	
	Decision: Approved.	
44.	Name and address of manufacturer / Applicant	M/s Venus Pharma 23 km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Chlorozine Injection
	Composition	Each ml contains:- Chlorpromazine hydrochloride….25mg
	Diary No. Date of R& I & fee	Dy No.17643, 11-05-2018, Rs.20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Chlorpromazine 2ml Injection Of Indus Pharma
	GMP status	GMP Certificate issued on 27-08-2018
	Remarks of the Evaluator	
	Decision of 286th meeting: Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. Evaluation by PEC: Applied formulation does not fall in the category of controlled drugs. Decision of 288th meeting: Registration Board decided to defer the case for the following reasons: For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs. For consideration of case on its turn. Submission by the firm: The firm has submitted GMP certificate No. 353/2019-DRAP(AD-1915187-536) dated 28/11/2019 issued on the basis of inspection conducted on 05/09/2019. The firm has submitted inspection report for renewal of DML dated 07/04/2017. As per report, Liquid injectable (ampoule) section is approved.	
	Previous Decision (M-312): Deferred for confirmation of approved manufacturing facility for Liquid Injectable (ampoule) section.	
	Firm submitted copy of renewal of Drug manufacturing License in which Liquid Ampoule Section (General) section mentioned.	

	Firm Submitted cGMP certificate on the basis of evaluation conducted on 22-08-2023 & 14-09-2023 in which Liquid Injectable (Vial & Ampoule) section mentioned.	
	Decision: Approved.	
45.	Name and address of manufacturer / Applicant	M/s Venus Pharma 23 km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fluzine Injection 25mg IM
	Composition	Each ml contains:- Fluphenazine decanoate….25mg
	Diary No. Date of R& I & fee	Dy No.17647, 11-05-2018, Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Synocate 25mg injection Reg # 056218
	GMP status	GMP Certificate issued on 27-08-2018
	Remarks of the Evaluator	
	Decision of 286th meeting: Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. Evaluation by PEC: Applied formulation does not fall in the category of controlled drugs. Decision of 288th meeting: Registration Board decided to defer the case for the following reasons: For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs. For consideration of case on its turn. Submission by the firm: The firm has submitted GMP certificate No. 353/2019-DRAP(AD-1915187-536) dated 28/11/2019 issued on the basis of inspection conducted on 05/09/2019. The firm has submitted inspection report for renewal of DML dated 07/04/2017. As per report, Liquid injectable (ampoule) section is approved.	
	Previous Decision (M-312): Deferred for confirmation of approved manufacturing facility for Liquid Injectable (ampoule) section.	
	Firm submitted copy of renewal of Drug manufacturing License in which Liquid Ampoule Section (General) section mentioned. Firm Submitted cGMP certificate on the basis of evaluation conducted on 22-08-2023 & 14-09-2023 in which Liquid Injectable (Vial & Ampoule) section mentioned.	
	Decision: Approved.	

Agenda of Evaluator PEC-V

Oral Powder (Veterinary) Section (New License) (14 Products/ 10 Molecules)		
46.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Ampro 50 Oral Powder
	Composition	Each 1000 g contains: Amprolium HCl 500 g
	Diary No. Date of R& I & fee	Challan Number: 46506362929 Paid Fee: 30000.0 Paid Date: 2024-05-08 Tracking ID:WGP-XNM-ZLXX Created on:May 13th, 2024
	Pharmacological Group	Antiprotozoal agent against Coccidiosis
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	50 gm De-Controlled

		100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	102216 "HANSTER-50% WATER SOLUBLE POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Species** Poultry, calves, lambs, young goats and sheep
	Decision: Approved.	
47.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Ampro 60 Oral Powder
	Composition	Each 1000 g contains: Amprolium HCl 600 g
	Diary No. Date of R& I & fee	Challan Number: 5112319618 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: Y4N-BV3-NT7L Created on: May 23rd, 2024
	Pharmacological Group	Antiprotozoal agent against Coccidiosis
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25 .0 kgDe-Controlled
	Me-too status	102217 "HANSTER-60% WATER SOLUBLE POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Species** Poultry, calves, lambs, young goats and sheep
	Decision: Approved.	
48.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Linco .H Oral Powder
	Composition	Each Gram Contains: Lincomycin HCl (equivalent to lincomycin) 400 mg.
	Diary No. Date of R& I & fee	Challan Number: 85870257976 Paid Fee: 30000.0 Paid Date: 2024-05-23

		Tracking ID: EZW-2G7-RVAR Created on: May 23rd, 2024
	Pharmacological Group	Antibacterials for systemic use; Lincosamides.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20 gm De-Controlled 50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	089826 "LINCOSEL-40 ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Species** sheep, Goat and chicken (broiler)
	Decision: Approved.	
49.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Tiphospho Oral Powder
	Composition	Each 100 Gram contains: Tylosin Tartrate 10 g Fosfomycin Calcium 20 g Sodium Phosphate 15 g Magnesium Phosphate 10 g Fructose-1,6-Di phosphate 18 g
	Diary No. Date of R& I & fee	Challan Number: 5697743381 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: 67W-7HX-Z1DM Created on: May 20th, 2024
	Pharmacological Group	Antibiotics/Anti-microbials
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	099386 "TAYFOT-30 ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Species** Poultry & Cage Birds (Pigeons, Canaries, Parrots) Dogs

	Decision: Approved.	
50.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Tybro CD Oral Powder
	Composition	Each kg contains: Tylosin Tartrate 100 g Doxycycline HCL 200 g Colistin Sulphate 500 MIU Bromhexine HCL 5 g
	Diary No. Date of R& I & fee	Challan Number: 418368267 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: 6VR-A78-BYNB Created on: May 20th, 2024
	Pharmacological Group	Antibiotics/Anti-microbials
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	089827 "RESPISIN ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Specie** For use in calves, Sheep, Goat, chickens and turkeys .
	Decision: Approved.	
51.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Tybro CD Plus Oral Powder
	Composition	Each kg contains: Tylosin Tartrate 200 g Doxycycline HCL 400 g Colistin Sulphate 500 MIU Bromhexine HCL 10 g
	Diary No. Date of R& I & fee	Challan Number: 450489688 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: WU6-MQ5-Q3W6 Created on: May 22nd , 2024
	Pharmacological Group	Antibiotics/Anti-microbials
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled

		1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	088045 "BROXTIN 24-POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Specie** For use in calves, Sheep, Goat, chickens and turkeys.
	Decision: Approved.	
52.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Tybro CD Super Oral Powder
	Composition	Each kg Contains: Tylosin Tartrate 300 g Doxycycline HCL 400 Colistin Sulphate 800 MIU Bromhexine HCL 5 g
	Diary No. Date of R& I & fee	Challan Number: 6121507433 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: UG8-L8G-RT3T Created on: May 22nd , 2024
	Pharmacological Group	Antibiotics/Anti-microbials
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	30 gm De-Controlled 50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	Viberdox(076412) Vibra Pharma
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Specie** For use in calves, Sheep, Goat, chickens and turkeys . **Shortcoming.** The provided Metoo could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
53.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Coli One Oral Powder
	Composition	Each gram contains: Colistin Sulphate 4800,000. IU

	Diary No. Date of R& I & fee	Challan Number: 5579051034 Paid Fee: 30000.0 Paid Date: 2024-05-09 Tracking ID: H54-ENW-RDEP Created on: May 13th , 2024
	Pharmacological Group	Polymyxin antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	50 gm De-Controlled 100 gmDe-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	053962 COLISMALL ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator V	**Target Specie** Cattle (calves), sheep (lambs), chickens and turkeys. Present in USP.
	Decision: Approved. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.	
54.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Neo One 70 Oral Powder
	Composition	Each 100 gram contains: Neomycin Sulphate 70 g
	Diary No. Date of R& I & fee	Challan Number: 867782600 Paid Fee: 30000.0 Paid Date: 2024-05-08 Tracking ID: WPM-YGZ-UR88 Created on: May 12th , 2024
	Pharmacological Group	intestinal anti-infectives, antibiotics.
	Type of Form	Form 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	087088 "ALVI NEO 70 ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator V	**Target Specie**

		Cattle (calves), Sheep, Goats, chickens (including laying hens),ducks, turkeys (including turkey hens), geese, quail and partridges.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
55.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Neo One 72 Oral Powder
	Composition	Each gram contains: Neomycin Sulphate 720 mg
	Diary No. Date of R& I & fee	Challan Number: 5818830645 Paid Fee: 30000.0 Paid Date: 2024-05-08 Tracking ID: UTN-ZWS-WUXU Created on: May 12th , 2024
	Pharmacological Group	Intestinal anti-infectives, antibiotics.
	Type of Form	Form 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	079295 "NEOVETZ 72% ORAL POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	Target species Cattle (calves), Sheep, Goats, chickens (including laying hens),ducks, turkeys (including turkey hens), geese, quail and partridges.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
56.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Oxyflone Oral Powder
	Composition	Each Gram Contains: Florfenicol 100 mg Neomycin Sulphate 150 mg Oxytetracycline HCL 300 mg
	Diary No. Date of R& I & fee	Challan Number: 11200871 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: 9B7-GNY-7NR8 Created on: May 16th , 2024
	Pharmacological Group	intestinal anti-infectives, antibiotics
	Type of Form	Form 5
	Finished product Specification	Innovators

	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	Florcycline N Plus (117203) Vetz Pharma
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Species** Cattle (calves), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quail and partridge. **Shortcoming** The provided Me too couldnot be confirmed.
	Decision: Approved	
57.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Amidolytes Oral Powder
	Composition	Each Kg Contains: Furosemide 20 g Calcium Carbonate 45 g Magnesium Sulphate 35 g Potassium Chloride 400 mg Manganese Sulphate 1 g Sodium Chloride 35 g
	Diary No. Date of R& I & fee	Challan Number: 52449093812 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: LAW-MAR-YN9R Created on: May 23rd , 2024
	Pharmacological Group	Loop Diuretic/ Flusher
	Type of Form	Form 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	20 gm De-Controlled 50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	071072 NEYPHRALYTE POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	Firm has submitted target species **"Poultry"**
	Decision: Approved.	

58.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	C Para One Oral Powder
	Composition	Each 100 Gram Contains: Paracetamol 2 g Vitamin C 20 g Calcium Carbonate 4.5 g Magnesium Sulphate 3.5 g Potassium Chloride 4 g
	Diary No. Date of R& I & fee	Challan Number: 61124824028 Paid Fee: 30000.0 Paid Date: 2024-05-13 Tracking ID: QR1-WXS-G5Q3 Created on: May 16th, 2024
	Pharmacological Group	Analgesic, Anti-pyretic, Stress Controller
	Type of Form	Form 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled 15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	Spin C (078239) Leads
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	Provide target specie.
	Decision: Approved. The firm will inform the target specie.	
59.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Doxy One Oral Powder
	Composition	Each Gram contains: Doxycycline Hyclate 500 mg.
	Diary No. Date of R& I & fee	Challan Number: 42819324167 Paid Fee: 30000.0 Paid Date: 2024-05-08 Tracking ID: RQ5-4S1-RRG1 Created on: May 13th, 2024
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	50 gm De-Controlled 100 gm De-Controlled 250 gm De-Controlled 500 gm De-Controlled 1.0 kg De-Controlled 2.5 kg De-Controlled 5.0 kg De-Controlled 10.0 kg De-Controlled

		15.0 kg De-Controlled 25.0 kg De-Controlled
	Me-too status	058717 SELDOX POWDER
	GMP status	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Remarks of the Evaluator [V]	**Target Specie** Cattle (pre-ruminating calf), Sheep, Goat, chicken (broilers, breeders, replacement chicks).
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

Agenda of Evaluator PEC-IX

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 22.01.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2022-2023

1824.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27488, Dt. 23.11.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 328385637
	The proposed proprietary name / brand name	**FINERIGET 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Finerenone……..10mg
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists ATC Code: C03DA05
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	The status in reference regulatory authorities	Kerendia 10mg and 20mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 22.01.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2022-2023

182	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi (DML No. 000284)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27489, Dt. 23.11.2023
	Details of fee submitted	PKR 75,000/- : Slip No. 0336344625
	The proposed proprietary name / brand name	**FINERIGET 20mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Finerenone……..20mg
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists ATC Code: C03DA05
	Reference to Finished product specifications	**As per Innovator's Specifications.**
	The status in reference regulatory authorities	Kerendia 10mg and 20mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1			

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Export Facilitation Case:
The EFD section vide letter No. 1-6/2019-PR-II (EFD) dated 29.05.2024 has informed that the Authority in 133rd meeting decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority bases, however a maximum of 15 such molecules shall be considered for grant of registration during a fiscal year.
As per letter of EFD section, the firm has requested following molecule against their benchmark achieved during the fiscal year 2019-2020

182	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**

	Name, address of Manufacturing site.	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: 4Q5-ZHQ-WG8L
	Details of fee submitted	PKR 30000/- : Slip No. 742075662
	The proposed proprietary name / brand name	**BETARULZ Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gam contains; Betamethasone Dipropionate Eq to Betamethasone…..0.5mg (0.05% w/w) Gentamicin Sulphate Eq to Gentamicin…….1mg (0.1 %w/w)
	Pharmacotherapeutic Group of (API)	Corticosteroids, dermatological preparations; Corticosteroids, potent, combinations with antibiotics ATC Code: D07CC01
	Reference to Finished product specifications	**Innovators Specifications.**
	The status in reference regulatory authorities	Mibetin 1 mg/g + 0.5 mg/g Cream MHRA Approved.
	For generic drugs (me-too status)	Betagenic Cream Reg. No. 027538 M/s ATCO

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.3	None of the excipients is listed as emulsifying agent. Please clarify which excipient is being used as an emulsifying agent in the formulation?	The firm has stated that they are following formulation of innovator product. Cetostearyl alcohol will be used as emulsifying agent.
2	3.2.P.8	Batch No. and details of drug substance used in manufacturing of trial batches is not mentioned.	Gentamicin: 220511038 Betamethasone: SCPL/BDP/003/2023
3	-	AD attested invoice or clearance certificate of both drug substance are required.	Submitted.

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

182	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Name, address of Manufacturing site.	**M/s Biolabs (pvt).ltd, Plot No. 145,Industrial Triangle, Kahuta road, Islamabad (DML No. 000286)**

	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: ASR-N3D-YBVN
	Details of fee submitted	PKR 75000/- : Slip No. 89722406
	The proposed proprietary name / brand name	**NALCIN 10mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule contains; Nalbuphine HCl……..10mg
	Pharmacotherapeutic Group of (API)	Morphinan derivatives ATC Code: N02AF02
	Reference to Finished product specifications	**Innovator Specifications.**
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml (USFDA Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of clearance certificate or AD attested invoice of drug substance is required.	Submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

182	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Name, address of Manufacturing site.	**M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad (DML No. 000628)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID: LMD-4EQ-ZB78
	Details of fee submitted	PKR 30000/- : Slip No. 0919947767
	The proposed proprietary name / brand name	**TURBO Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains; Terbinafine HCl……10mg (1%)
	Pharmacotherapeutic Group of (API)	Corticosteroids, dermatological preparations; Other antifungals for topical use ATC Code: D01AE15
	Reference to Finished product specifications	**JP Specifications.**

	The status in reference regulatory authorities	Lamisil AT 1% Cream MHRA Approved.
	For generic drugs (me-too status)	Lamisil cream 1%

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Clearance certificate or copy of AD attested invoice of drug substance is required,	Submitted

Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Agenda of Evaluator PEC-XI

Case No. 01: Deferred Registration applications of Human Drugs on form 5F (New sections):

182	Name, address of Applicant / Marketing Authorization Holder	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 25-03-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/99-Lic (Vol-II) dated 07th July 2020 specifying Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 18532 dated 24-07-2023
	Details of fee submitted	Rs.30,000/- dated 19-06-2023 (Slip#691693865537)
	The proposed proprietary name / brand name	**Safpime 500mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) Eq. to Cefepime……500mg Ampoule: Water for injection…….5ml
	Pharmaceutical form of applied drug	Intravenous/Intramuscular
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics

	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's, 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefepime Hydrochloride (500mg, 1g, 2g) for injection by M/s Qilu Pharma USFDA Approved
	For generic drugs (me-too status)	Maxipime 500mg Injection by M/s GSK Pakistan Limited (Reg#25548)
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Maxum 500mg Injection IM/IV by M/s Curexa Health Pvt. Ltd. (Highnoon Laboratories Ltd.)
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit, system suitability.
STABILITY STUDY DATA		
Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At &	

	Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	CEIV/B2012114		
Description of Pack (Container closure system)	Filled and sealed glass vial packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 vial	500 vial	500 vial
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023 Firm has submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 10153/2020/DRAP-AD-VII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kgm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.5.2	• The applied label claim shall include only description of dry powder injection only, while for diluent separate registration application shall be applied	• The firm submitted that our formulation is IV Injection, the diluent used with injection is WFI. Registration letter of WFI is submitted
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit	• Sterile powder for injection
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Birwadi, Mahad-402302,, District: Raigad, India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer • Justification shall be submitted for selecting the limit of water content test as 8.0%-11.0% in batch analysis instead of NMT 4.0 % by drug product manufacturer as per drug substance manufacturer specifications	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies is not submitted • As the material complies with USP specifications, arginine test is not performed in USP. That's why arginine test was not performed by the manufacturer. USP monograph is submitted • The firm submitted that corrected limit is NMT 4% & revised COA is submitted
3.2.P.8	• Clarification shall be submitted, as the batch size mentioned in BMR is 500vials while 300vials in stability summary sheets. • Justify the delay between manufacturing of trial batches (12-2021) and initiation of stability studies (09-02-2022.). • Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Justify the results of assay test based on a single chromatographic area	• The firm submitted that batch size of 500 vials was prepare in which 300 vials were placed for stability testing, while 200 vials were placed as reference sample • The firm submitted that delay occurred due to non-availability of reference standard for standardization of testing procedure • The firm submitted Letter No. 10153/2020/DRAP-AD-VIII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kg issued by AD (I&E) DRAP Lahore dated 24-07-2020. However, no invoice or clearance certificate is submitted

		• Audit trail reports on product testing is submitted • As per USP monograph testing of cefepime was carried out. So, the single chromatographic area was observed

Previous Decision (M-335th-DRB): Deferred for submission of following:

- The applied label claim shall include description of dry powder injection only
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
- Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer
- Justification for the delay between manufacturing of trial batches and initiation of stability studies
- Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.
- Justification for the results of assay test based on a single chromatographic area.

Firm's response:

S No	Observations	Firm's Response
1	• The applied label claim shall include description of dry powder injection only	The firm has again applied the label claim: Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) equivalent to Cefepime …….. 500mg/vial Ampoule: Water for injection …….. 5 ml
2	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted
3	• Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	• The firm submitted that USP monograph of Cefepime Inj does not contain assay of arginine content. Rather it contains Identification of Arginine by TLC. We have performed TLC identification at initial testing of trial Batches. TLC chromatogram copy is submitted
4	• Justification for the delay between manufacturing of trial batches and initiation of stability studies	• The firm submitted that Laboratory was trying to obtain the reference standard of Arginine from the supplier to perform its quantitative analysis by supplier method. After two month delay, laboratory decided to continue it through USP method by performing TLC identification test. Due to this reason two month gap occurred between the trial and its initial testing.
5	• Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.	Firm has submitted copy of commercial invoice cleared dated 05-04-2021 specifying 10kg of Cefepime Hydrochloride USP (L-Arginine). The invoice is cleared by AD (I&E) DRAP.
6	• Justification for the results of assay test based on a single chromatographic area.	USP monograph of Cefepime Inj requires system suitability under Assay. System suitability requirement is as under Sample: Standard solution Suitability requirements Tailing factor: NMT 1.5 Saffron result with standard solution is 1.45

		Relative standard deviation: NMT 2.0% Saffron result with standard solution is 0.52% System suitability test is performed according to USP general chapter of Chromatography <621>. Analysis Samples: Standard solution and Sample solution Calculate the percentage of C19H24N60SS2 in the portion of Cefepime for Injection taken: Result =(ru/rs) x (Cs/Cu) x 100 ru =peak response from the Sample solution rs =peak response from the Standard solution Cs = concentration of USP Cefepime Hydrochloride RS in the Standard solution(mg/mL) Cu = nominal concentration of cefepime in the Sample solution(mg/mL) According to system suitability requirement, If RSD of standard solution meets the requirement, then analysis is carried out on sample solution. And single injection of sample will produce reliable results, because system suitability has been established by USP required criteria. Saffron result of Tailing factor and RSD% meets the system suitability requirement, so sample results are reliable.

Decision: Approved with following label claim:
Each Vial contains:
Cefepime HCl (with L-Arginine) equivalent to Cefepime …….. 500mg

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

183	Name, address of Applicant / Marketing Authorization Holder	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 25-03-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	**New Section**

		Firm has submitted copy of letter No. F. 1-12/99-Lic (Vol-II) dated 07th July 2020 specifying Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 19298 dated 03-08-2023
	Details of fee submitted	Rs.30,000/- dated 19-06-2023 (Slip#518159184555)
	The proposed proprietary name / brand name	**Safpime 1g IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) Eq. to Cefepime……1g Ampoule: Water for injection…….10ml
	Pharmaceutical form of applied drug	Intravenous/Intramuscular
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's, 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefepime Hydrochloride (500mg, 1g, 2g) for injection by M/s Qilu Pharma USFDA Approved
	For generic drugs (me-too status)	Maxipime 1g Injection by M/s GSK Pakistan Limited (Reg#25549)
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Maxum 1g Injection IM/IV by M/s Curexa Health Pvt. Ltd. (Highnoon Laboratories Ltd.)
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	CEIV/B2012114		
Description of Pack (Container closure system)	Filled and sealed glass vial packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 vial	500 vial	500 vial
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto

		19-10-2023 Firm has submitted License retention certificate of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 10153/2020/DRAP-AD-VII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kgm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.5.2	• The applied label claim shall include only description of dry powder injection only, while for diluent separate registration application shall be applied	• The firm submitted that our formulation is IV Injection, the diluent used with injection is WFI. Registration letter of WFI is submitted
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit	• Sterile powder for injection
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Birwadi, Mahad-402302,, District: Raigad, India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies is not submitted • As the material complies with USP specifications, arginine test is not performed in USP. That's why arginine test was not performed by the manufacturer. USP monograph is submitted • The firm submitted that corrected limit is NMT 4% & revised COA is submitted

	• Justification shall be submitted for selecting the limit of water content test as 8.0%-11.0% in batch analysis instead of NMT 4.0 % by drug product manufacturer as per drug substance manufacturer specifications	
3.2.P.8	• Stability summary sheet for batch No#T-003 at real time conditions is not submitted • Justify the delay between manufacturing of trial batches (12-2021) and initiation of stability studies (09-02-2022.). • Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Justify the results of assay test based on a single chromatographic area	• No reply submitted • The firm submitted that delay occurred due to non-availability of reference standard for standardization of testing procedure • The firm submitted Letter No. 10153/2020/DRAP-AD-VIII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kg issued by AD (I&E) DRAP Lahore dated 24-07-2020. However, no invoice or clearance certificate is submitted • Audit trail reports on product testing is submitted • As per USP monograph testing of cefepime was carried out. So, the single chromatographic area was observed

Previous Decision (M-335th-DRB): Deferred for submission of following:

- The applied label claim shall include only description of dry powder injection only
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
- Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer
- Justification for the delay between manufacturing of trial batches and initiation of stability studies.
- Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.
- Justification for the results of assay test based on a single chromatographic area

Firm's response:

S No	Observations	Firm's Response
1	• The applied label claim shall include description of dry powder injection only	The firm has again applied the label claim: Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) equivalent to Cefepime …….. 1.0g/vial Ampoule: Water for injection …….. 10ml
2	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted
3	• Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer	• The firm submitted that USP monograph of Cefepime Inj does not contain assay of arginine content. Rather it contains Identification of Arginine by TLC. We have performed TLC identification at initial testing of trial Batches. TLC chromatogram copy is submitted

4	• Justification for the delay between manufacturing of trial batches and initiation of stability studies	• The firm submitted that Laboratory was trying to obtain the reference standard of Arginine from the supplier to perform its quantitative analysis by supplier method. After two month delay, laboratory decided to continue it through USP method by performing TLC identification test. Due to this reason two month gap occurred between the trial and its initial testing.
5	• Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.	Firm has submitted copy of commercial invoice cleared dated 05-04-2021 specifying 10kg of Cefepime Hydrochloride USP (L-Arginine). The invoice is cleared by AD (I&E) DRAP.
6	• Justification for the results of assay test based on a single chromatographic area.	USP monograph of Cefepime Inj requires system suitability under Assay. System suitability requirement is as under Sample: Standard solution Suitability requirements Tailing factor: NMT 1.5 Saffron result with standard solution is 1.45 Relative standard deviation: NMT 2.0% Saffron result with standard solution is 0.52% System suitability test is performed according to USP general chapter of Chromatography <621>. Analysis Samples: Standard solution and Sample solution Calculate the percentage of C19H24N60SS2 in the portion of Cefepime for Injection taken: Result =(ru/rs) x (Cs/Cu) x 100 ru =peak response from the Sample solution rs =peak response from the Standard solution Cs = concentration of USP Cefepime Hydrochloride RS in the Standard solution(mg/mL) Cu = nominal concentration of cefepime in the Sample solution(mg/mL) According to system suitability requirement, If RSD of standard solution meets the requirement, then analysis is carried out on sample solution. And single injection of sample will produce reliable results, because system suitability has been established by USP required criteria. Saffron result of Tailing factor and RSD% meets the system suitability requirement, so sample results are reliable.

Approved with following label claim:
Each Vial contains:
Cefepime HCl (with L-Arginine) equivalent to Cefepime …….. 1.0g

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 7,500/- for correction/pre-approval change/ in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 02: Deferred Registration applications of Human Drugs on form 5F (New sections):

183	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 19986 dated 11-08-2023
	Details of fee submitted	Rs.30,000/- dated 21-07-2023 (Slip#02373419703)
	The proposed proprietary name / brand name	**Flucin Lotion 0.01%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Fluocinolone Acetonide……0.01%
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Derma-Smoothe/FS Topical Oil, 0.01% USFDA Approved
	For generic drugs (me-too status)	Oleofin 0.01% Oil (Topical Oil) by M/s Derma Techno Pakistan (Reg#111740)
	Name and address of API manufacturer.	M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th street, West Area of Tianjin Economic-

		Technological Development Area, Tianjin 300462, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Derma Smooth by M/s Valor Pharmaceutical.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability, robustness, limit of detection and quantitation limit.

STABILITY STUDY DATA

Manufacturer of API	M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China
API Lot No.	NES211113
Description of Pack (Container closure system)	A muticolored 120ml labelled plastic bottle pack in unit carton with enclosed leaflet
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	FLU 22-134	FLU 22-135	FLU 22-136
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	09-10-2022	09-10-2022	09-10-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Pranami Drugs Pvt. Ltd., Plot No. 7290 GIDC Industrial Estate, Ankleshwar, Dist. Bharuch, India.., issued by Food and Drugs Control Administration Gujarat State India valid till 19-08-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 14-05-2022 for import of 1.0kg of Fluocinolone Acetonide USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 14-05-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [xi]:

Section	Observations	Firm's Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Standardize your label claim in line with reference formulation along with submission of applicable fee	• The firm has submitted the label claim for **Flucin Topical Oil 0.01% w/v** without submission of fee. Each ml Contains: Fluocinolon Acetonide……0.1mg However the reference product recommends label claim in w/w units.
1.5.10	• You have applied for lotion while the reference formulation is topical oil clarify?	• The firm submitted that it is topical solution in oil and applied under the lotion section. But mistakenly in cover letter it was written lotion instead of topical oil. Please consider the application as oil and grant us registration for the said for fluocinolone acetonide as topical oil.
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of	• The firm has submitted copy of DML#JIN20150001 of M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th

	origin is required • GMP certificate of a different manufacturer is submitted than that the details data of which is submitted in this section and in module 3	street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China valid till 11-10-2025. • DML of relevant drug substance manufacturer is submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted
3.2.S.7	• Submit stability study data of drug substance as per zone IV-A conditions till claimed shelf life	• Not submitted
3.2.P.8	• Raw data sheets of drug product at initial time point of stability study shall be submitted	• Raw data sheets of drug product at initial time point of stability study is submitted

Previous Decision (M-335th-DRB): Deferred for submission of following:

- Standardized label claim in line with reference formulation along with submission of applicable fee
- Stability study data of drug substance as per zone IV-A conditions till claimed shelf life

Firm's Response:

S No#	Observations	Firm's Response
1	• Standardized label claim in line with reference formulation along with submission of applicable fee	• Firm has submitted revised label claim for Flucin Topical Oil 0.01% w/w as per reference formulation without submission of fee. The revised label claim is as under: Each gram Contains: Fluocinolon Acetonide……0.1mg
2	• Stability study data of drug substance as per zone IV-A conditions till claimed shelf life	• Submitted

Decision: Approved with following label claim:
Each gram Contains:
Fluocinolon Acetonide……0.1mg

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of strength of applied formulation), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case No. 03; Deferred registration applications of Human Drugs on Form 5F (Routine)

1832.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract

		giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 15-02-2022 based on inspection conducted on 02-02-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-22/95-Lic (Vol-II) dated 20-11-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23275 dated 17-08-2022
	Details of fee submitted	Rs.30,000/- dated 26-11-2021 (Deposit slip#1597194661)
	The proposed proprietary name / brand name	**Dexalan 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole……30mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3x10' s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 30 mg by M/s The Searle Company Ltd. (Reg#86978)
	Name and address of API manufacturer.	Source of pellets: M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Wilsop 30mg capsule by M/s Wilson's Pharmaceuticals. CDP has been performed against the same product Wilsop 30mg capsule by M/s Wilson's Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Repeatability, intermediate Precision, robustness, linearity.

STABILITY STUDY DATA

Manufacturer of API	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.		
API Lot No.	DLP664		
Description of Pack (Container closure system)	Alu-alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-015	T-016	T-017
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	01-2021	01-2021	01-2021

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of cGMP certificate of M/s Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019. The firm have submitted copy of DML of M/s Vision Pharmaceuticals (Pvt) Ltd., renewed w.e.f. 02-12-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 04-12-20 for purchase of 4kg of Dexlansoprazole DDR Pellets 22.5% from M/s Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted
3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical method validation studies are not submitted

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response

1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee	• The firm has submitted revised label claim as per reference formulation along with submission of Rs. 7500/- on deposit slip No#900251417479. The revised label claim is as under: Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets eq. to Dexlansoprazole……..30 mg
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Additional Director DRAP valid upto 13-06-2024
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Analytical Method Verification studies is not submitted
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted	• No justification is submitted • Firm has provided details of reference product Product name: Wilsop 30mg capsule Manufacturer: Wilson's Pharmaceuticals Batch (10): 1542 Mfg date: 08-2020 Exp date: 08-2022
3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical method validation studies are not submitted	• The firm has submitted revised finished product specifications in which tests of content uniformity and loss on drying has been included. • The firm submitted that specificity test is typically part of verification process for pharmacopieal methods. Since the product already meets manufacturer specifications, further verification may not be deemed necessary as validation has already been provided.

Decision: Deferred for submission of following:

- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance**
- **Justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying).**
- **Results of specificity test in analytical method validation studies of applied product**

1833.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 15-02-2022 based on inspection conducted on 02-02-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-22/95-Lic (Vol-II) dated 20-11-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23276 dated 17-08-2022
	Details of fee submitted	Rs.30,000/- dated 26-11-2021 (Deposit slip#92167515)
	The proposed proprietary name / brand name	**Dexalan 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole……60mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3x10' s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 60mg by M/s The Searle Company Ltd. (Reg#086979)
	Name and address of API manufacturer.	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Wilsop 60mg capsule by M/s Wilson's Pharmaceuticals. CDP has been performed against the same product Wilsop 60mg capsule by M/s Wilson's Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Repeatability, intermediate Precision, robustness, linearity.

STABILITY STUDY DATA	
Manufacturer of API	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.
API Lot No.	DLP664
Description of Pack (Container closure system)	Alu-alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-018	T-019	T-020
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of cGMP certificate of M/s Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019. The firm have submitted copy of DML of M/s Vision Pharmaceuticals (Pvt) Ltd., renewed w.e.f. 02-12-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 04-12-20 for purchase of 4kg of Dexlansoprazole DDR Pellets 22.5% from M/s Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted

3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical method validation studies are not submitted
3.2.P.8	• Date of manufacturing of trial batches as per submitted summary sheets is 02-2021 while date of initiation of stability study is 01-2021, clarify?

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee	• The firm has submitted revised label claim as per reference formulation along with submission of Rs. 7500/- on deposit slip No#55356426. The revised label claim is as under: Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets eq. to Dexlansoprazole……..60 mg
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Additional Director DRAP valid upto 13-06-2024
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Analytical Method Verification studies is not submitted
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted	• No justification is submitted • Firm has provided details of reference product Product name: Wilsop 60mg capsule Manufacturer: Wilson's Pharmaceuticals Batch (10): 1602 Mfg date: 11-2020 Exp date: 011-2022
3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical	• The firm has submitted revised finished product specifications in which tests of content uniformity and loss on drying has been included. • The firm submitted that specificity test is typically part of verification process for pharmacopieal methods. Since the product already meets manufacturer specifications,

	method validation studies are not submitted	further verification may not be deemed necessary as validation has already been provided.
3.2.P.8	• Date of manufacturing of trial batches as per submitted summary sheets is 02-2021 while date of initiation of stability study is 01-2021, clarify?	• The firm submitted that stability study started in February 2021, matching the manufacturing date of the trial batches. This ensures consistency with the information provided in the attached stability summary sheets.

Decision: Deferred for submission of following:

- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance**
- **Justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying).**
- **Results of specificity test in analytical method validation studies of applied product**

Agenda of Evaluator PEC-XIII

Case No. 01. New DML/New Section cases.

M/s Qadir Pharmaceuticals**. (New DML)**

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following seven (07) sections to M/s Qadir Pharmaceuticals

1. Tablet (General)
2. Capsule (General)
3. Oral Liquid (General)
4. Liquid Injectable – Vial & Ampoule (General)
5. Capsule (Cephalosporin)
6. Dry Powder Injectable (Cephalosporin)
7. Oral Dry Powder Suspension (Cephalosporin)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

70.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 1AG-PQR-36AS dated 08-05-2024.
	Details of fee submitted	Rs.30,000/- vide slip No. 2159915248 dated 18-04-2024.
	The proposed proprietary name / brand name	**Dicloqad 75mg/3ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains; Diclofenac Sodium…….25mg
	Pharmacotherapeutic Group of (API)	NSAIDs.
	Reference to Finished product specifications	Innovator's Specifications.

	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too status)	Voren injection 75mg/3ml, Asian Continental pharma, Reg. No. 007737.

STABILITY STUDY DATA

API Lot No.	DFS/12110478.		
Description of Pack (Container closure system)	Clear colorless liquid Injection filled in type A glass Ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AMPT07	AMPT08	AMPT09
Batch Size	3000 ampoules.	3000 ampoules.	3000 ampoules.
Manufacturing Date	04-2023	04-2023	04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted a list of their product with registration letter issued to them that were approved in 333rd meeting of registration board on form 5F.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/114344/2022/11/41922 dated 07-09-2022 issued in the name of M/s AARTI DRUGS LTD issued by FDA Bandra(E), Mumbai valid till 06-09-2025.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 No. K-1538507558641 mentioning Diclofenac Sodium BP 1kg from M/s AARTI DRUGS LTD dated 06-02-2023.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S. No.	Section	Observation	Reply by the firm
1.	3.2.S.7.3	Stability of the drug substance as per Zone IV shall be submitted.	Firm has submitted new stability data for the drug substance as per Zone IV for batch No. DFS/301002, DFS/305060 & DFS/309136.

2.	3.2.P.2.2	Justification shall be submitted for not performing PE studies against innovator product.	Firm has submitted that as per CTD guidance document, PE studies can also be performed against the comparator product. So we also perform the PE studies against the local brand.
3.	3.2.P.8	Justification shall be submitted for not including Sterility and Bacterial endotoxin tests in stability data sheets.	Firm has submitted that they have performed both the test at initial stage and will also perform at the end stage. However, during compilation they were not included in stability data sheets. They also submitted new stability data sheets wherein they have added sterility tests.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

71.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 3PG-M1N-HYNYdated 08-05-2024.
	Details of fee submitted	PKR 30,000/- vide slip No. 92722727083 Dated 18-04-2024.
	The proposed proprietary name / brand name	**Fit-D3 5mg/1ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains; Cholecalciferol …….….5mg
	Pharmacotherapeutic Group of (API)	Vitamin D.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	ANSM approved.
	For generic drugs (me-too status)	Indrop D injection. Neutro Pharma, Reg. No., Reg. No. 023170.

STABILITY STUDY DATA

API Lot No.	CH23031001.
Description of Pack (Container closure system)	Clear colorless oily liquid Injection filled in type I glass ampoule.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AMPT01	AMPT02	AMPT03
Batch Size	1500 Ampoules	1500 Ampoules	1500 Ampoules
Manufacturing Date	07-2023	07-2023	07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted copy of DML (GAN20170017) dated 28-05-2022 issued by Food and Drugs Control Administration China.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Form 5 No. K-1784507558953 mentioning Vitamin-D3 (Cholecalciferol) dated 10-05-2023. Online clearance certificate is submitted. Certificate is valid till 17-05-2027.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted analytical record for product testing.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Evaluation by PEC:

S. No.	Section	Observation	Reply by the firm
1.	1.5.6	This section has mentioned BP specifications while BP monograph is for 7.5mg strength. Clarification shall be submitted.	Firm has submitted that monograph of vitamin D injection is available in BP that's why we used the same specifications.
2.	3.2.P.8.3	Stability data sheets have mentioned glass A ampoule. Clarification shall be submitted.	Firm has submitted that it was a typo error. It is Glass I ampoule.
3.	3.2.P.8	Justification shall be submitted for not including Sterility and Bacterial endotoxin tests in stability data sheets.	Firm has submitted that they have performed both the test at initial stage and will also perform at the end stage. However, during compilation they were not included in stability data sheets. They also submitted new stability data sheets wherein they have added sterility tests.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

72.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.**

	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Ghar Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 37Z-S6M-UXRW dated 01-03-2024.
	Details of fee submitted	PKR 30,000/- vide slip No. 0592480683 Dated 16-10-2023.
	The proposed proprietary name / brand name	**Q-Phin 1000mg/100mL Infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol …… 1000mg
	Pharmacotherapeutic Group of (API)	Analgesic Antipyretic Drug.
	Reference to Finished product specifications	Innovator's Specifications.
	MHRA approved.	MHRA approved.
	Provas Infusion 1000mg/100ml, Sami Pharmaceuticals, Reg. No. 053223.	Provas Infusion 1000mg/100ml, Sami Pharmaceuticals, Reg. No. 053223.

STABILITY STUDY DATA

API Lot No.	00510921/335/2022.		
Description of Pack (Container closure system)	Glass Ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	INF0001	INF0002	INF0003
Batch Size	50 Vials	50 Vials	50 Vials
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted a list of their product with registration letter issued to them that were approved in 333rd meeting of registration board on form 5F.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (204/2022-DRAP) (AD/159531263130-536) dated 22-11-2022 issued on the basis of inspection conducted on 18-11-2022.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 1598 dated 07-01-2023 from M/s Pharmagen Limited.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.

Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Evaluation by PEC:

S. No.	Section	Observation	Reply by the firm
1.	3.2.S.7.3	Clear and readable copies of stability data sheets of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
2.	3.2.P.2.2	Justification shall be submitted for not performing PE studies against innovator product.	Firm has submitted that as per CTD guidance document, PE studies can also be performed against the comparator product. So we also perform the PE studies against the local brand.
3.	3.2.P.8	• Justification shall be submitted for not including Sterility and Bacterial endotoxin tests in stability data sheets. • Raw data for stability data at different time interval shall be submitted. • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted that they have performed both the test at initial stage and will also perform at the end stage. However, during compilation they were not included in stability data sheets. They also submitted new stability data sheets wherein they have added sterility tests. Submitted. Submitted. Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

73.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swera Pharmaceuticals, Plot # 27, Street # S-4, Industrial Area, Rawat.**
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals, Plot # 27, Street # S-4, Industrial Area, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking ID 3W8-41M-BQA9 dated 19-04-2024.

	Details of fee submitted	PKR 30,000/- vide slip No. 47304672570 Dated 04-01-2024.
	The proposed proprietary name / brand name	**Swedogesic Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Paracetamol ……..... 450mg Orphenadrine citrate ……..... 35mg
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic and muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Norgesic Tablets, TGA approved.
	For generic drugs (me-too status)	Pauco Tablets by M/s Dew-max Pharma Rawat, Reg. No. 103597

STABILITY STUDY DATA

API Lot No.	Paracetamol: 00510911/083/2022 Orphenadrine citrate: HOCCPO069		
Description of Pack (Container closure system)	PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-T019	RD-T019	RD-T019
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	Firm has new DML and products are approved on form %F in various meetings of Registration Board.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Firm has submitted copy of GMP Certificate (204/2022-DRAP) (AD/159531263130-536) dated 22-11-2022 issued on the basis of inspection conducted on 18-11-2022. **Orphenadrine citrate:** Firm has submitted copy of license retention certificate issued by DCA Telangana issued in the name of M/s Harika Drugs Private Limited valid till 31/12/2027.
Documents for the procurement of API with approval from DRAP (in case of import).	Paracetamol: Local source and invoice submitted. Orphenadrine citrate: Firm has submitted copy of Form 5 attested by DRAP, Islamabad and clearance certificate for M/s Dew Max pharmaceuticals mentioning 200.00Kg of Orphenadrine citrate attested by DRAP, Islamabad 18-11-2020 specifying
Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

chromatograms, Raw data sheets, COA, summary data sheets etc.	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm is new DML. In nearby future we will put efforts to be 21 CFR complaint.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S. No.	Section	Observation	Reply submitted by the firm
1.	3.2.S.4.2	Analytical procedure for Orphenadrine citrate from Finished Product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.4	Specifications of Orphenadrine citrate has mentioned assay limit of 98.5% - 101% while the COA of the Drug product manufacturer has mentioned 99% 101%. Clarification shall be submitted.	Firm has submitted that it was typographic error. However, results are within the limit. They further submitted new COA with correct specifications.
3.	3.2.P.3.5	Process validation protocol shall be submitted.	Submitted.
4.	3.2.P.8	Loan letter for API Orphenadrine citrate shall be submitted.	Firm has submitted loan letter from M/s Dew max Pharma.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 02. Deferred application of Form 5F.

74.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry Powder suspension (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14706 dated 12-06-2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 874651822159 Dated 06-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 125mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 125mg. Potassium Clavulanate eq. Clavulanic Acid……. 31.25mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	60ml, 75ml, 90ml, 100ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 125 mg/31.25mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Augmentin 125 mg/31.25mg, GSK Pakistan, Reg. No. 009264.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**Amoxicillin trihydrate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general

		properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (02NB2205007) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin trihydrate:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions: Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months Real time: 5°C ± 3°C for 36 months. Batches: (NA-201106301, NA-201106302 & NA-201106303)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Augmentin dry powder suspension 125mg with B. No. PV8L, mfg. date 06-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.
API Lot No.	Not provided.
Description of Pack (Container closure system)	Amber colour Glass Bottle properly sealed with cap, labelled and packed in cardboard carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	<u>Amoxicillin Trihydrate:</u> Firm has submitted copy of GMP certificate No. DC/A-4/GMP/2022/2804 dated 07-09-2022 issued by Food Safety and Drugs Control Commissionerate (Drugs Control Wing) Rajasthan, India valid till 08-09-2023. However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted. <u>Potassium Clavulanate:</u> Not submitted.
3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance	Submitted. However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash. Firm has submitted specifications for the drug substance i.e. mixture of potassium

		manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate. Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	Submitted. However, the submitted analytical procedure is completely different from BP monograph. Concentration of the standard solution for amoxicillin and potassium Clavulanate are different from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical method has mentioned potassium Clavulanate as reference standard.
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of	Not submitted. Not submitted.

		assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths of Falamox suspension.	Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore. As per record of the executed BMRs of the trial batches with strength of 125mg/5ml, 37.23mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 37.23 x 12 = 446.76mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 446.76 = 670,140mg or 670gm. As per record of the executed BMRs of the trial batches with strength of 250mg/5ml, 74.38mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 74.38 x 12 = 892.56mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 892.56 = 1,338,840mg or 1338gm. As per record of the executed BMRs of the trial batches with strength of 400mg/5ml, 67.83mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 67.83 x 12 = 813.96mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 813.96 = 1,220,940mg or 1220gm Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.

Decision of 330th meeting of Registration Board: Deferred for following;

- Justification shall be submitted for change in the submitted specifications i.e. assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.
- Justification shall be submitted for submission of COA of the drug substance i.e. Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.
- Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.
- Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.

- Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.
- Raw data sheets for calculation of assay at each time point with formula shall be submitted.
- Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.

Reply submitted by the firm;

S. No.	Reason for deferment	Reply submitted by the firm
1.	Justification shall be submitted for change in the submitted specifications i.e. assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.	Firm has submitted revised specifications as per drug substance manufacturer. However fee required for revision of specifications is not submitted.
2.	Justification shall be submitted for submission of COA of the drug substance i.e. Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.	Firm has submitted that due to compilation error, COA of Ampicillin trihydrate was submitted instead of Amoxicillin. They also submitted Amoxicillin trihydrate from drug substance manufacturer.
3.	Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.	Firm has submitted that analytical method is adjusted as per actual practice, in accordance with USP <621> Chromatography and system suitability parameters complies the specification. The same had been validated.
4.	Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.	Firm has submitted that Testing was carried out by using working standard of lithium Clavulanate provided by supplier. COA of the same had already been submitted. They also submitted COA from supplier.
5.	Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.	Revised stability data sheets are submitted by the firm with inclusion of API lot No. I.e. Potassium Clavulanate: 4132201012. Amoxicillin: 000120/841/2021.
6.	Raw data sheets for calculation of assay at each time point with formula shall be submitted.	Submitted.
7.	Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.	Firm has submitted that Approx. 1Kg of Potassium Clavulanate vide clearance certificate (E 2827420227964) dated 26-Sep-2022 was used for the product development. For Stability batches, 5Kg of Potassium Clavulanate was taken as loan from Stallion Pharmaceuticals. They further submitted loan letter from M/s Stallion pharmaceuticals mentioning Meropenem trihydrate, Imipenem and Cilastatin and potassium Clavulanate with Syloid (1:1) with computerized clearance certificate No. E-405342829253 dated 16-03-2022 attested by Assistant Director I&E, DRAP, Lahore

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
75.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry Powder suspension (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14707 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 165628659 Dated 05-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 250mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 250mg. Potassium Clavulanate eq. Clavulanic Acid …….. 62.50mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	60ml & 90ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 250mg/62.50mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Zamoclav suspension, Zafa Pharmaceutical, Reg. No. 035386.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.

		Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**Amoxicillin trihydrate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (02NB2205007) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin trihydrate:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions: Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months Real time: 5°C ± 3°C for 36 months. Batches: (NA-201106301, NA-201106301 & NA-201106301)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control

		of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Augmentin dry powder suspension 250mg with B. No. SY2R, mfg. date 05-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Amber colour Glass Bottle properly sealed with cap, labelled and packed in cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	<u>Amoxicillin Trihydrate:</u> Firm has submitted copy of GMP certificate No. DC/A-4/GMP/2022/2804 dated 07-09-2022 issued by Food Safety and Drugs Control Commissionerate (Drugs Control Wing) Rajasthan, India valid till 08-09-2023. However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted. <u>Potassium Clavulanate:</u> Not submitted.
3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Submitted. However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash. Firm has submitted specifications for the drug substance i.e. mixture of potassium Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be	Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.

		submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	Submitted. However, the submitted analytical procedure is completely different from BP monograph. Concentration of the standard solution for amoxicillin and potassium Clavulanate are different from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical method has mentioned potassium Clavulanate as reference standard.
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths of Falamox suspension.	Not submitted. Not submitted. Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore. As per record of the executed BMRs

			of the trial batches with strength of 125mg/5ml, 37.23mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 37.23 x 12 = 446.76mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 446.76 = 670,140mg or 670gm. As per record of the executed BMRs of the trial batches with strength of 250mg/5ml, 74.38mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 74.38 x 12 = 892.56mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 892.56 = 1,338,840mg or 1338gm. As per record of the executed BMRs of the trial batches with strength of 400mg/5ml, 67.83mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 67.83 x 12 = 813.96mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 813.96 = 1,220,940mg or 1220gm Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.

Decision: Deferred for following;

- Justification shall be submitted for change in the submitted specifications i.e assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.
- Justification shall be submitted for submission of COA of the drug substance i.e Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.
- Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.
- Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.
- Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.
- Raw data sheets for calculation of assay at each time point with formula shall be submitted.
- Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.

Reply submitted by the firm:

S. No.	Reason for deferment	Reply submitted by the firm
1.	Justification shall be submitted for change in the submitted specifications i.e. assay, water content and sulphated ash between	Firm has submitted revised specifications as per drug substance manufacturer.

	the specifications of drug substance manufacturer and drug product manufacturer.	However fee required for revision of specifications is not submitted.
2.	Justification shall be submitted for submission of COA of the drug substance i.e. Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.	Firm has submitted that due to compilation error, COA of Ampicillin trihydrate was submitted instead of Amoxicillin. They also submitted Amoxicillin trihydrate from drug substance manufacturer.
3.	Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.	Firm has submitted that analytical method is adjusted as per actual practice, in accordance with USP <621> Chromatography and system suitability parameters complies the specification. The same had been validated.
4.	Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.	Firm has submitted that Testing was carried out by using working standard of lithium Clavulanate provided by supplier. COA of the same had already been submitted. They also submitted COA from supplier.
5.	Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.	Revised stability data sheets are submitted by the firm with inclusion of API lot No. I.e. Potassium Clavulanate: 4132201012. Amoxicillin: 000120/841/2021.
6.	Raw data sheets for calculation of assay at each time point with formula shall be submitted.	Submitted.
7.	Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.	Firm has submitted that Approx. 1Kg of Potassium Clavulanate vide clearance certificate (E 2827420227964) dated 26-Sep-2022 was used for the product development. For Stability batches, 5Kg of Potassium Clavulanate was taken as loan from Stallion Pharmaceuticals. They further submitted loan letter from M/s Stallion pharmaceuticals mentioning Meropenem trihydrate, Imipenem and Cilastatin and potassium Clavulanate with Syloid (1:1) with computerized clearance certificate No. E-405342829253 dated 16-03-2022 attested by Assistant Director I&E, DRAP, Lahore

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

76.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry Powder suspension (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14709 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0036909442 Dated 06-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 400mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 400mg. Potassium Clavulanate eq. Clavulanic Acid ….. 57mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	35ml & 70ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 400mg/57mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Clav Forte 400mg + 57mg/5ml Dry Suspension, Amrose Pharmaceuticals, Reg. No. 058102.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**<u>Amoxicillin trihydrate:</u>** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (02NB2205007) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin trihydrate:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions: Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months Real time: 5°C ± 3°C for 36 months. Batches: (NA-201106301, NA-201106301 & NA-201106301)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Augmentin dry powder suspension 400mg with B. No. RY4P, mfg. date 06-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	**Amoxicillin Trihydrate:**	

	Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Amber colour Glass Bottle properly sealed with cap, labelled and packed in cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	<u>Amoxicillin Trihydrate:</u> Firm has submitted copy of GMP certificate No. DC/A-4/GMP/2022/2804

			dated 07-09-2022 issued by Food Safety and Drugs Control Commissionerate (Drugs Control Wing) Rajasthan, India valid till 08-09-2023. However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted. <u>Potassium Clavulanate:</u> Not submitted.
3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Submitted. However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash. Firm has submitted specifications for the drug substance i.e. mixture of potassium Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate. Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished	Submitted.

		product shall be submitted.	However, the submitted analytical procedure is completely different from BP monograph. Concentration of the standard solution for amoxicillin and potassium Clavulanate are different from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical method has mentioned potassium Clavulanate as reference standard.
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths of Falamox suspension.	Not submitted. Not submitted. Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore. As per record of the executed BMRs of the trial batches with strength of 125mg/5ml, 37.23mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 37.23 x 12 = 446.76mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 446.76 = 670,140mg or 670gm. As per record of the executed BMRs of the trial batches with strength of 250mg/5ml, 74.38mg/5ml quantity of potassium Clavulanate is used. 60ml of bottle is used in stability data. 74.38 x 12 = 892.56mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 892.56 = 1,338,840mg or 1338gm. As per record of the executed BMRs of the trial batches with strength of 400mg/5ml, 67.83mg/5ml quantity of potassium Clavulanate is used.

			60ml of bottle is used in stability data. 67.83 x 12 = 813.96mg/bottle. Total of 03 trial batches with batch size of 500 each were manufactured. 1500 x 813.96 = 1,220,940mg or 1220gm Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.

Decision of 330th meeting of Registration Board: Deferred for following;

- Justification shall be submitted for change in the submitted specifications i.e assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.
- Justification shall be submitted for submission of COA of the drug substance i.e Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.
- Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.
- Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.
- Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.
- Raw data sheets for calculation of assay at each time point with formula shall be submitted.
- Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.

Reply submitted by the firm:

S. No.	Reason for deferment	Reply submitted by the firm
1.	Justification shall be submitted for change in the submitted specifications i.e. assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.	Firm has submitted revised specifications as per drug substance manufacturer. However fee required for revision of specifications is not submitted.
2.	Justification shall be submitted for submission of COA of the drug substance i.e. Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.	Firm has submitted that due to compilation error, COA of Ampicillin trihydrate was submitted instead of Amoxicillin. They also submitted Amoxicillin trihydrate from drug substance manufacturer.
3.	Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.	Firm has submitted that analytical method is adjusted as per actual practice, in accordance with USP <621> Chromatography and system suitability parameters complies the specification. The same had been validated.
4.	Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.	Firm has submitted that Testing was carried out by using working standard of lithium Clavulanate provided by supplier. COA of the same had already been submitted. They also submitted COA from supplier.
5.	Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.	Revised stability data sheets are submitted by the firm with inclusion of API lot No. I.e. Potassium Clavulanate: 4132201012. Amoxicillin: 000120/841/2021.
6.	Raw data sheets for calculation of assay at each time point with formula shall be submitted.	Submitted.

7.	Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.	Firm has submitted that Approx. 1Kg of Potassium Clavulanate vide clearance certificate (E 2827420227964) dated 26-Sep-2022 was used for the product development. For Stability batches, 5Kg of Potassium Clavulanate was taken as loan from Stallion Pharmaceuticals. They further submitted loan letter from M/s Stallion pharmaceuticals mentioning Meropenem trihydrate, Imipenem and Cilastatin and potassium Clavulanate with Syloid (1:1) with computerized clearance certificate No. E-405342829253 dated 16-03-2022 attested by Assistant Director I&E, DRAP, Lahore

Decision: Approved. Registration letter will be issued after submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XV

Oral Liquid (Veterinary) (New License) (21 Products/ 10 Molecules)		
77.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Vanide Oral Liquid
	Composition	Each ml Contains: Levamisole HCl B.P___15mg Oxyclozanide B.P___30mg Cobalt Sulphate MS__1.67mg Sodium Selenite B.P__0.50mg
	Tracking Id, date & fee	HZ6-2YQ-WGL1 Dated: 14-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 40710835610)
	Pharmacological Group	Anthelmintics, Imidazothiazoles
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Mallzan Plus (046689) Mallard Pharmaceuticals (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, calves, sheep, goat
	Decision:Approved.	
78.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Vanide Plus Oral Liquid
	Composition	Each ml Contains: Levamisole HCl B.P___30mg Oxyclozanide B.P___60mg Cobalt Sulphate MS___7.46mg Sodium Selenite B.P___0.76mg

	Tracking Id, date & fee	SS9-89W-THAU, dated: 14-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 5953851369)
	Pharmacological Group	Anthelmintics, Imidazothiazoles
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	LEOX D.S Plus (Elko) (031595) Elko Organization (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, calves, sheep, goat
	Decision: Approved.	
79.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Oxa Plus Oral Liquid
	Composition	Each ml Contains: Oxyclozanide B.P__62.5mg Oxfendazole B.P__22.65mg Cobalt Sulphate MS___1.67mg Sodium Selenite B.P___0.5mg
	Tracking Id, date & fee	T8M-8UG-WPZV Dated: 14-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 1552032986)
	Pharmacological Group	Anthelmintics, Dewormers
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Punch Drench (032206) Selmore pharmaceuticals (Pvt) Ltd. Oxarex Gold Drench (031455) Star Laboratories (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, Buffalow, sheep, goat
	Decision: Approved.	
80.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	One Target Oral Liquid
	Composition	Each 100ml Contains: Triclabendazole B.P___12g Albendazole B.P___10g Ivermectin B.P___0.2g
	Tracking Id, date & fee	N27-TZQ-JRUY Dated:14-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 9681837803)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Abentin Drench (088089) Selmore Pharmaceuticals (Pvt) Ltd. Thunder Drench (058941) Star laboratories (Pvt) Ltd.
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep, goat
	Decision: Approved.	
81.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.

	Brand Name +Dosage Form + Strength	Alba One 2.5% Oral Liquid
	Composition	each ml Contains: Albendazole B.P……..25 mg
	Tracking Id, date & fee	X36-JTA-AVNN Dated: 12-05-2024 RS 30,000/- Dated 08-05-2024 (Slip No. 322918785)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	B.P Vet. Specification
	Pack size & Demanded	30ml, 60ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L, 15.0L, 25.0L
	Me-too status	Sanazole Oral Solution (023483) Each ml Contains: - Albendazole 25mg of M/s. SANNA LABS FAISALABAD
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep, goat
	Decision: Approved.	
82.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Alba One 10% Oral Liquid
	Composition	Each ml Contains: Albendazole B.P ___100mg
	Tracking Id, date & fee	DNL-G7H-GU8M Dated: 14-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 0428664029)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	B.P Vet. Specification
	Pack size & Demanded	30ml, 60ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L, 15.0L, 25.0L
	Me-too status	1- Albasym Suspension (022742) Symans Pharmaceuticals (Pvt) Ltd. 2-Albensel 10 drench (043143) Selmore Pharmaceuticals (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Alba One 11.25% Oral Liquid
	Composition	Each ml Contains: Albendazole B.P ___112.5mg
	Tracking Id, date & fee	DNL-G7H-GU8M Dated: 23-05-2024, RS 30,000/- Dated 22-05-2024 (Slip No. 38875655666)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	B.P Vet. Specification
	Pack size & Demanded	30ml, 60ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L, 15.0L, 25.0L
	Me-too status	Albamall 11.25% (046687) (Mallard) Pharmaceuticals (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep
	Decision: Approved.	

84.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Alba One 12.5% Oral Liquid
	Composition	Each ml Contains: Albendazole B.P……125mg
	Tracking Id, date & fee	U6Z-UT9-XUGD Dated: 06-05-2024, RS 30,000/- Dated 06-05-2024 (Slip No. 38875655666)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	B.P Vet. Specification
	Pack size & Demanded	30ml, 60ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L, 15.0L, 25.0L
	Me-too status	Vetazole 12.5% Oral Liquid (079280) Vetz Pharmaceuticals (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep
	Decision: Approved.	
85.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Onemizole 1.5% Oral Liquid
	Composition	Each ml Contains: Levamisole HCl B.P…..15mg
	Tracking Id, date & fee	B39-XG9-JS5S Dated: 15-05-2024, RS 30,000/- Dated 08-06-2024 (Slip No. 01565388819)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	1- Nilverm Drench (002108) ICI Pakistan Ltd. 2-Vernil Solution (006865) Star Laboratories (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep
	Decision: Approved.	
86.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Onemizole 3% Oral Liquid
	Composition	Each ml Contains: Levamisole HCl B.P ____30mg
	Tracking Id, date & fee	IT8-Z9Z-T3JY Dated:16-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 0412670481)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Mallworm DS (058929) Mallard pharmaceutical (PVT) LTD. Each 100ml Contains: - Levamisole Hcl……30mg
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle, sheep

		Levarold Oral Suspension 3% of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK.
	Decision: Approved	
87.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	One Mec 1% Oral Liquid
	Composition	Each ml Contains: Ivermectin B.P___10mg
	Tracking Id, date & fee	WPI-AR2-ANDQ Dated: 14-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 64820112)
	Pharmacological Group	Anthelmintics, endectocides
	Type of Form	Form 5
	Finished product Specification	B.P Vet Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Faro-mac Oral liquid (058915) Mallard pharmaceutical (PVT) LTD.
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: horses, cows, camels, goats, or sheep
	Decision:Approved	
88.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	One Mec 0.08% Oral Liquid
	Composition	Each ml Contains: Ivermectin B.P__0.8mg
	Tracking Id, date & fee	NN3-QAJ-B66SDated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 49141787714)
	Pharmacological Group	Anthelmintics, endectocides
	Type of Form	Form 5
	Finished product Specification	B.P Vet Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Ivotec Drench (026541) Star Laboratories (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: horses, cows, camels, goats, or sheep
	Decision:Approved	
89.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	One Mec 0.24% Oral Liquid
	Composition	Each ml Contains: Ivermectin B.P……2.4mg
	Tracking Id, date & fee	NGM-ZGG-PLTL Dated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 20245255608)
	Pharmacological Group	Anthelmintics, endectocides
	Type of Form	Form 5
	Finished product Specification	B.P Vet Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	ELVOMEC DRENCH 0.24% (063730) Elko Organization (Pvt) Ltd. Each ml contains: -

		Ivermectin ……0.24%
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: horses, cows, camels, goats, or sheep
	Decision:Approved	
90.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	En-C-One Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin HCl USP___10g Colistin Sulphate USP_50,000,000 IU
	Tracking Id, date & fee	B42-9QA-17EB Dated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 81245602272)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Alviflox Oral Liquid (087087) Mallard Pharmaceuticals (Pvt) Ltd
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision:Approved	
91.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	En-C-One Plus Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin HCl USP_____20g Colistin Sulphate USP__50,000,000 IU
	Tracking Id, date & fee	EEA-5E4-J1PJ Dated: 09-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 36220559)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	M flox-c liquid (089835) m/s. Majestic pharma, Plot # 21, phase-1A, M-3, industrial city, Faisalabad. Each 100ml contains: - Enrofloxacin……..…… 20g Colistin sulphate…….50 MIU
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision: Approved with the following label claim as per available Me-Too. **Each 100ml contains: -** **Enrofloxacin……..…… 20g** **Colistin sulphate…….50 MIU** **Registration Board further decided that registration letter will be issued after submission of Fee of Rs.30,000/- for revision of salt form of active as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

92.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Onero 10% Oral Liquid
	Composition	Each ml Contains: Enrofloxacin USP _____100mg
	Tracking Id, date & fee	M9W-GDE-36MQ Dated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 3812424127)
	Pharmacological Group	Fluoroquinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Ceriflox 10% oral solution(020788) Star Laboratories (Pvt) Ltd.
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision:Approved	
93.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Onero 20% Oral Liquid
	Composition	Each ml Contains: Enrofloxacin USP _____200mg
	Tracking Id, date & fee	YTE-VE4-E44E Dated: 15-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 59422496)
	Pharmacological Group	Fluoroquinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	1- Envet 20% Oral Liquid (116901) Vetz Pharmaceuticals (Pvt) Ltd. 2-Enroxsel 20 Oral Solution (049634) Selmore Pharmaceuticals (PVT) LTD
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision: Approved.	
94.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Onero 25% Oral Liquid
	Composition	Each ml Contains: Enrofloxacin USP _____250mg
	Tracking Id, date & fee	76X-U72-USXX Dated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 998142524)
	Pharmacological Group	Fluoroquinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Enrotril 25%(112113) Mallard Pharmaceuticals (Pvt) Ltd

	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision: Approved.	
95.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Flor-C One Oral Liquid
	Composition	Each ml Contains: Florfenicol MS _____230mg Colistin Sulphate B.P_____50MIU
	Tracking Id, date & fee	PJZ-4AR-UV2M Dated: 15-05-2024, , RS 30,000/- Dated 09-05-2024 (Slip No. 947356859)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Olsticol Oral Solution (096837) M/S. Ras Pharmaceuticals (Pvt) Ltd.,25-Km Lahore Road, Multan. Each 100ml Contains: - Florfenicol …….23.0gm Colistin Sulphate……....50MIU
	GMP status	New License issue dated 25-04-2024
	Remarks of the Evaluator	**Target Species**: Cattle (calves), sheep (lambs) and chickens
	Decision: Approved.	
96.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	Flor-C Plus Oral Liquid
	Composition	Each ml Contains: Florfenicol MS _____250mg Colistin Sulphate B.P_____50MIU
	Tracking Id, date & fee	4A1-7BQ-E6BR Dated: 15-05-2024 RS 30,000/- Dated 09-05-2024 (Slip No. 01688139578)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Flocol Oral Liquid (074082) Dmaarson Pharmaceuticals
	GMP status	New License
	Remarks of the Evaluator	**Target Species**: Cattle (calves), sheep (lambs) and chickens
	Decision: Approved.	
97.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Place: Plot No. N-28-II-A, S.I.T.E, Kotri, Jamshoro, Sindh, Pakistan.
	Brand Name +Dosage Form + Strength	One Cosin Oral Liquid
	Composition	Each ml Contains: Tilmicosin as (Tilmicosin Phosphate)……250mg
	Tracking Id, date & fee	G9Z-IV3-VLWP Dated: 15-05-2024, RS 30,000/- Dated 09-05-2024 (Slip No. 03361216084)
	Pharmacological Group	Macrolide Antibiotic

	Type of Form	Form 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded	50ml, 100ml, 250ml, 500ml, 1.0L, 2.5L, 5.0L, 10.0L 15.0L, 25.0L
	Me-too status	Tilmosin Oral Solution (Reg.no. 090649) M/S. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th Km Ferozepur Road, Lahore.
	GMP status	New License
	Remarks of the Evaluator	**Target Species**: Broiler chickens, breeding poultry, hens and turkeys, Sheep and Goat
	Decision: Approved.	

Agenda of Evaluator PEC-XX

98.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Ltd F-95,Off Hub River Road, S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 30.8.2019 based on inspection dated 28.08.2019 valid for 1 year from the date of issue
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for Regularization of existing facility dated 22-06-2018 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35496 (R&I) DRAP, dated 07/12/2022
	Details of fee submitted	PKR 75,000/- Dated 22-06-2022
	The proposed proprietary name / brand name	Trela 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Trelagliptin Succinate eq to Trelagliptin ……..……..….50mg
	Pharmacotherapeutic Group of (API)	Antidiabetic (Dipeptidyl peptidase 4 inhibitor)
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 10's, 14's and 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA (Japan) Approved
	For generic drugs (me-too status)	OWT Tablet 50mg by PharmEvo Karachi

	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co Ltd No 21 Huancheng West Road Anqing Anhui China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(20180606, 20180613, 20180620)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Zafatek 50mg tablet (Batch No 522052) by M/s Takeda Pharmaceutical (Exp date 05/2025)** Quality parameters such as appearance, average weight, hardness dissolution, DT, assay, microbial limit and impurity were compared. CDP has been performed against the same brand that is **Zafatek 100mg tablet (Batch No 522052) by M/s Takeda Pharmaceutical** in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The % drug release in all three mediums is more than 85% in 15 min hence f2 value is not calculated.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Anhui Haikang Pharmaceutical Co Ltd No 21 Huancheng West Road Anqing Anhui China		
API Lot No.	21072401		
Description of Pack (Container closure system)	Alu-PVC packaging		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-01-2022	12-01-2022	12-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate dated 09/09/2019 issued by Anqing Biomedical Industry Association valid till 09th September 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# WD202105041 dated 27th July 2021, with received quantity i.e. 2Kg) for the purchase of Trelagliptin Succinate from Anhui Haikang Pharmaceutical Co. Ltd China and clearance certificate from DRAP dated 12/08/2021 (batch no. 21072401)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	Firm has provided GMP certificate dated 03.08.2022 based on inspection dated May 16, 17,20,23 and 24, 2022 valid for 2 years from the date of issue	Complied
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the	Provided	Complied

	batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3		

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

Agenda of Evaluator PEC-XXI

Agenda Item No. I:
Application(s) for New Registration (Human-Local) - New License / New Section.

99.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safina Pharmaceuticals (Pvt.) Ltd., 17-KM, Lahore Sheikhupura Road, Distt. Sheikhupura.**
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17-KM, Lahore Sheikhupura Road, Distt. Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Tracking ID: V4P-XS1-JJL1
	Details of fee submitted	PKR 30,000/- dated May 15, 2023. Challan / Receipt # 85633482867
	The proposed proprietary name / brand name	**ESOSAF 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole magnesium trihydrate equivalent to Esomeprazole … 20mg
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	NEXIUM 20mg Capsules (USFDA Approved)
	For generic drugs (me-too status)	NEXUM 20mg Capsules of M/s Getz Pharma (Pvt.) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies have been communicated to the firm:

i. Label claim needs to be corrected as per Innovator / Reference Product as follows: -

Each capsule contains:
Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 20mg

ii. 2.3.P.3.1 Please provide GMP Certificate of FPP Manufacturer (not older than 03 Years).

iii. 3.2.P.2.2.1 (c) Comparative Dissolution Study Results have not been submitted, rather only protocol has been enclosed in this section. Please clarify.

iv.	As mentioned in 3.2. P. 5.6 Justification of Specifications as well as claimed USP Monograph recommends Dissolution Analysis to be performed on Acid Stage as well as Buffer Stage, whereas 3.2. P.5.4 Batch Analysis and 3.2.P.8 Stability Study Data Results show that Dissolution Test have been performed on single stage. Please justify.	
Decision: **Registration Board deferred the case for submission of reply to the above cited shortcomings.**		
100.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safina Pharmaceuticals (Pvt.) Ltd., 17-KM, Lahore Sheikhupura Road, Distt. Sheikhupura.**
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17-KM, Lahore Sheikhupura Road, Distt. Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Tracking ID: 2BQ-HNY-QWL9
	Details of fee submitted	PKR 30,000/- dated May 15, 2023. Challan / Receipt # 0562333214
	The proposed proprietary name / brand name	**ESOSAF 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole magnesium trihydrate equivalent to Esomeprazole … 40mg
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	NEXIUM 40mg Capsules (USFDA Approved)
	For generic drugs (me-too status)	NEXUM 40mg Capsules of M/s Getz Pharma (Pvt.) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC (XXI):		
The following deficiencies have been communicated to the firm: i. Label claim needs to be corrected as per Innovator / Reference Product as follows: - *Each capsule contains:* *Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 40mg* ii. 2.3.P.3.1 Please provide GMP Certificate of FPP Manufacturer (not older than 03 Years). iii. 3.2.P.2.2.1 (c) Comparative Dissolution Study Results have not been submitted, rather only protocol has been enclosed in this section. Please clarify. iv. As mentioned in 3.2. P. 5.6 Justification of Specifications as well as claimed USP Monograph recommends Dissolution Analysis to be performed on Acid Stage as well as Buffer Stage, whereas 3.2. P.5.4 Batch Analysis and 3.2.P.8 Stability Study Data Results show that Dissolution Test have been performed on single stage. Please justify. v. The submitted Audit Trails Reports are for **Esomeprazole 20mg Capsules.** Please justify.		
Decision: **Registration Board deferred the case for submission of reply to the above cited shortcomings.**		
101.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals 204, Street No. 1, I-10/3 Industrial Area, Islamabad.**

	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals 204, Street No. 1, I-10/3 Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Tracking ID: DL1-UX3-8EZY
	Details of fee submitted	PKR 30,000/- dated Nov 13, 2023. Challan / Receipt # 024382293716
	The proposed proprietary name / brand name	**SUCROFER 100mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml ampoule contains: Iron sucrose complex (as elemental iron) … 100mg
	Pharmacotherapeutic Group of (API)	B03AC, Iron, parenteral preparations.
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule, (TGA Australia Approved).
	For generic drugs (me-too status)	BISLERI-S 100mg/5ml Injection of M/s SAMI Pharmaceuticals (Pvt.) Limited, B#010K.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies have been communicated to the firm: -

i. The enclosed GMP Certificate of API Manufacturer was valid till 18-05-2023. Please provide valid GMP Certificate.
ii. 3.2.P.2.3 In Pharmaceutical Equivalence Study it has been mentioned that study was conducted with SUCROFER **10mg/5ml Injection**. Please clarify.
iii. Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence.
iv. 3.2.P.5.1 Please mention USP glass Type of ampoule used for filling.
v. 3.2.P.5.1 BP in its Monograph recommends tests for '**content of Iron, Fe**' as well as '**content of Sucrose**' both. However, the same has not been conducted by you. Please justify.
vi. 3.2.P.5.1 Furthermore, the tests for 'Osmolality' as well as 'Molecular Weight Determination' as mentioned in enclosed BP Monograph, have also not been conducted in this section. Please justify.
vii. 3.2.P.8 Please provide Stability Study Data along with attested respective documents like Raw data sheets, COA, summary data sheets etc., for **6th Month Testing Interval** of all 03 Trials.

Decision:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Agenda of Evaluator PEC-XXIII

Registration applications of New DML (Veterinary)

a. New Cases

I. M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK. CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of DML by way of formulation with following section:

1. Oral Powder (Penicillin) Vet. Section

Accordingly, firm has applied for following products for consideration by the Registration Board:

Section	No. of Applied Products	No. of Molecule Applied
Oral Powder (Penicillin) Vet. Section	19	10

Oral Powder (Penicillin) Vet. Section
(19 Products/ 10 Molecules)

102.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	BROLIN Powder
	Composition	Each 1000g powder contains: Amoxicillin as Trihydrate B.P …… 100g Lincomycin HCl …….. 50g Colistin Sulphate B.P…….. 500MIU Bromhexine HCl ……. 5g
	Diary No. Date of R& I & fee	Dy.No 2S2-266-3BRB dated 28-05-2024 Rs 30,000/- (Deposit No. 0135384465)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	COLAB W/S POWDER (079839) DECENT Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each 1000g powder contains: Amoxicillin Trihydrate B.P ……100g Lincomycin HCl…….. 50g Colistin Sulphate B.P……500MIU Bromhexine HCl ……. 5g
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: **"Each 1000g powder contains:** **Amoxicillin Trihydrate B.P ……100g** **Lincomycin HCl…….. 50g** **Colistin Sulphate B.P……500MIU** **Bromhexine HCl ……. 5g"**	
103.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	C MOXIN 15% Powder
	Composition	Each 1000Gm powder contains Amoxicillin As Trihydrate B.P ……15% Colistin Sulphate B.P……..550MIU
	Diary No. Date of R& I & fee	Dy.No ULL-E56-6GPZ dated 28-05-2024 Rs 30,000/- (Deposit No. 5258106085)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications

	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	AM COL W/S POWDER (073944) Inshal Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each 1000gm powder contains:- Amoxicillin Trihydrate…15% Colistin Sulphate……550 MIU
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: "Each 1000gm powder contains:- Amoxicillin Trihydrate…15% Colistin Sulphate……550 MIU"	
104.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	C MOXIN 20% Powder
	Composition	Each 100Gm powder contains Amoxicillin As Trihydrate B.P ……20Gm Colistin Sulphate B.P……80MIU
	Diary No. Date of R& I & fee	Dy.No Z3G-W4S-QHY9 dated 28-05-2024 Rs 30,000/- (Deposit No. 478304816757)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	AMOXITIN-C W/S POWDER (071062) ATTABAK Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision:	
105.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	C MOXIN 23% Powder
	Composition	Each 100Gm powder contains: Amoxicillin As Trihydrate B.P ……23Gm Colistin Sulphate B.P……100MIU
	Diary No. Date of R& I & fee	Dy.No EN4-SS5-UMR3 dated 28-05-2024 Rs 30,000/- (Deposit No. 2100284043)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	PENTA MOX W/S POWDER (071018) BIOGEN Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each 100gm contains:- Amoxicillin trihydrate……23gm Colistin sulphate…100 MIU
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: "Each 100gm powder contains:- Amoxicillin Trihydrate…23g Colistin Sulphate……100 MIU"	

106.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	C MOXIN 50% Powder
	Composition	Each 100Gm powder contains Amoxicillin As Trihydrate B.P ……50Gm Colistin Sulphate B.P……50MIU
	Diary No. Date of R& I & fee	Dy.No Q3T-8UJ-LS85 dated 28-05-2024 Rs 30,000/- (Deposit No. 7010745494)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	AMOX-C MAARSON W/S POWDER (071054) ATTABAK Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
107.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	C MOXIN 60% Powder
	Composition	Each Gm powder contains Amoxicillin as Trihydrate B.P ……200mg Colistin Sulphate B.P……60,00,000IU
	Diary No. Date of R& I & fee	Dy.No 3M6-QSA-24N3 dated 28-05-2024 Rs 30,000/- (Deposit No. 202414568030)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	ALC MOXIN-C W/S POWDER (075662) BREEZE Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each gm contains:- Amoxycillin Trihydrate ……..200mg Colistin Sulphate…... 6,000,000 iu
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: **"Each gm powder contains:-** **Amoxicillin Trihydrate…200mg** **Colistin Sulphate……6 MIU"**	
108.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CILLIN-50% Powder
	Composition	Each 1000Gm powder contains: Amoxicillin As Trihydrate B.P ……500Gm
	Diary No. Date of R& I & fee	Dy.No E3B-Q2E-1TT8 dated 28-05-2024 Rs 30,000/- (Deposit No. 060055179352)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Specifications

	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	RYMOX-50% W/S POWDER (069665) ZUMRAS Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
109.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CILLIN-70% Powder
	Composition	Each 100Gm powder contains Amoxicillin As Trihydrate BP….. 80g EQ to 70g Amoxicillin Base
	Diary No. Date of R& I & fee	Dy.No X84-W3N-JHG6 dated 28-05-2024 Rs 30,000/- (Deposit No. 18247427)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	PRIMOX-70% W/S POWDER (074032) PRIX Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
110.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	TRI CIN 5 Powder
	Composition	Each 100Gm powder contains Spectinomycin Sulphate…….5Gm Lincomycin HCL…….5Gm Amoxicillin As Trihydrate……10Gm
	Diary No. Date of R& I & fee	Dy.No SG7-7LT-7PT8 dated 28-05-2024 Rs 30,000/- (Deposit No. 9119288096)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	SPECTOMOX-L W/S POWDER (102077) GRAND Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each 100gm contains:- Lincomycin hcl……...5gm Spectinomycin sulphate….……5gm Amoxicillin trihydrate…10gm
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: **"Each 100gm contains:-** **Lincomycin hcl……...5gm** **Spectinomycin sulphate….……5gm** **Amoxicillin trihydrate…10gm "**	
111.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	TRI CIN 8.8 Powder

	Composition	Each 100Gm powder contains Lincomycin HCl…….. ……8.8Gm Spectinomycin Sulphate…….8.8Gm Amoxicillin As Trihydrate……20Gm
	Diary No. Date of R& I & fee	Dy.No RXP-LTR-9JN7 dated 28-05-2024 Rs 30,000/- dated 20-02-2024 (Deposit No. 56293339)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	SPECTOMOX FORTE W/S POWDER (102078) GRAND Pharma
	GMP status	New DML
	Remarks of the Evaluator	Change label claim according to me-too as follows along with submission of fee: Each 100gm contains:- Amoxicillin trihydrate….20gm Lincomycin hcl……8.8gm Spectinomycin sulphate……...8.8gm
	Decision: Approved. Firm shall submit PKR 30,000/- fee as per S.R.O. 496(I)/2023 dated 17-04-2023 for pre-registration change in label claim as follows: "Each 100gm contains:- Amoxicillin trihydrate….20gm Lincomycin hcl……8.8gm Spectinomycin sulphate……...8.8gm"	
112.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MOX SEL E Powder
	Composition	Each Gm powder contains: Amoxicillin Trihydrate BP EQ To Base…….200mg Lincomycin HCL BP EQ To Base ……88mg Spectinomycin Sulphate BP VET EQ To Base…. 88mg Vitamin E Acetate USP……30mg
	Diary No. Date of R& I & fee	Dy.No D3N-WPA-J3WY dated 28-05-2024 Rs 30,000/- (Deposit No. 9835291352)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	LINCOMOXEL PLUS W/S POWDER (080960) SELMORE Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
113.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	NOXLIN Powder
	Composition	Each gm powder contains: Phenoxymethylpenicillin ……...293mg eq. to Potassium phenoxymethylpenicillin ……..… 325mg
	Diary No. Date of R& I & fee	Dy.No JYY-SXQ-PVHB dated 28-05-2024 Rs 30,000/- (Deposit No. 04110362123)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	FENAPEN W/S POWDER (106727) MYLAB Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
114.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CALLIN 24 Powder
	Composition	Each 100Gm powder contains Amoxicillin Trihydrate 20g eq. to 17.392g Amoxicillin base Colistin Sulphate ……4Gm Clavulanic Acid as Potassium Clavulanate …4Gm
	Diary No. Date of R& I & fee	Dy.No BPG-G8E-54LL dated 28-05-2024 Rs 30,000/- (Deposit No. 71965876198)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	MOXILAV-C W/S POWDER (082791) LEADS Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
115.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MOX TIN C Powder
	Composition	Each Kg powder contains: Amoxicillin As Trihydrate B.P ……100Gm Colistin Sulphate B.P……..50Gm Neomycin Sulphate…….200Gm
	Diary No. Date of R& I & fee	Dy.No DWH-ZYM-UVAB dated 28-05-2024 Rs 30,000/- (Deposit No. 301534183)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	NEO AC W/S POWDER (079844) DECENT Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
116.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	NEW PSB Powder
	Composition	Each Kg powder contains Procaine Penicillin BP……..…12Gm Streptomycin Sulphate BP…….36Gm Zinc Bacitracin 10% BP Vet……52Gm Neomycin Sulphate BP…….10g
	Diary No. Date of R& I & fee	Dy.No RAQ-GAB-Z8WH dated 28-05-2024 Rs 30,000/- (Deposit No. 632345767)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	PSB-EXCEL POWDER (082489) NAWAN Laboratories
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
117.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARK COMOX 15% Powder
	Composition	Each 1000Gm powder contains Amoxicillin as Trihydrate B.P ……150Gm Colistin Sulphate B.P……500MIU Dextrose Anhydrous BP QS…….1000Gm
	Diary No. Date of R& I & fee	Dy.No 7VL-BQ9-PNZM dated 28-05-2024 Rs 30,000/- (Deposit No. 9197645718)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	POTENCIL W/S POWDER (079843) DECENT Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
118.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARK COMOX 20% Powder
	Composition	Each 1000Gm powder contains Amoxicillin as Trihydrate B.P ……200Gm Colistin Sulphate B.P……800MIU Dextrose Anhydrous BP QS…….1000Gm
	Diary No. Date of R& I & fee	Dy.No NZT-X1U-4VH2 dated 28-05-2024 Rs 30,000/- (Deposit No. 3689734162)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	ASCOT W/S POWDER (079841) DECENT Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
119.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARK COMOX 23% Powder
	Composition	Each 1000Gm powder contains Amoxicillin as Trihydrate B.P ……230Gm Colistin Sulphate B.P……1000MIU Dextrose Anhydrous BP QS…….1000Gm
	Diary No. Date of R& I & fee	Dy.No AQG-LN4-ZS6A dated 28-05-2024 Rs 30,000/- dated 20-02-2024 (Deposit No. 278475623533)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	SENACILIN W/S POWDER (079845) DECENT Pharma
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
120.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARK COMOX 50% Powder
	Composition	Each 100Gm powder contains Amoxicillin as Trihydrate B.P ……50Gm Colistin Sulphate B.P……50MIU Dextrose Anhydrous BP QS…….100Gm
	Diary No. Date of R& I & fee	Dy.No ERQ-UPA-3QX3 dated 28-05-2024 Rs 30,000/- (Deposit No. 1625451666)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 10000gm; Decontrolled
	Me-too status	EUROMOX-50 W/S POWDER (080156) DECENT PHARMA
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	

Agenda of Evaluator PEC-XXIV

ADDITIONAL AGENDA IMPORT

Anticancer: Added on priority in the light of the decision of 257th meeting of Registration Board

121.	Name, address of Applicant / Importer	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial zone, Karaj, Iran.
	Name, address of manufacturer(s)	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial zone Karaj Iran.
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: 8HP-28L-15N5: 15-05-2024
	Details of fee submitted	PKR 300,000/-: 16-04-2024
	The proposed proprietary name / brand name	**Tinlo 150mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Erlotinib (as Hydrochloride) …….150mg
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	Any other.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 665/32562) issuance date 9-7-2022 issued by Food and Drug Administration, Ministry of Health and Medical Education, Iran. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement.
	The status in reference regulatory authorities	Tarceva®150mg F.C Tablet. (Roche pharma) USFDA Approved
	For generic drugs (me-too status)	Tarceva 150mg Tablet Marketed by: Roche Pakistan Ltd.
	Proposed pack size & MRP	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Section#	Observation	Firm's Response
1.	1.3	Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement. Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant firm shall be submitted.	Reply of the firm is still irrelevant as the submitted LOA is still same as the previously submitted one as it is not evident which is the Manufacturer of the drug product.
2.	1.5.6	Submitted specifications declared as "In house specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC	Firm has stated that they will follow Innovator's specification, however, fee is not submitted for revision of specifications.
3.	3.2.S.4	Drug substance specifications, analytical procedure, analytical method verification studies and batch analysis COA shall be submitted form the drug product manufacturer i.e., M/s Actero Middle East, Iran	Firm has stated, "We have asked the principal M/s Actero Middle East to provide us Drug Substance specifications, analytical procedures, analytical method verification and batch analysis COA, we will submit the data as provided by the principle".

4.	3.2.P.2.2.1	Product development report in section 3.2.P.2 has been submitted from M/s Hetero Labs. India Justification shall be submitted on this regard. Justification shall be submitted for use of 1%SLS in the dissolution medium for the performance of CDP studies. Comparative dissolution studies in three mediums of physiological pH 12, 4.5 & 6.8 shall be submitted, since firm has submitted CDP studies in 0.1N HCl medium only.	Firm has stated, We have asked the principal to provide product PDR, they will also provide the Comparative Dissolution profile in three mediums, we will submit that as provided by the principal". However, firm has attached a document regarding the use of 1% SLS IN 0.1N HCl in which principle states "We Actero Middle east Company hereby notify concerning the dissolution study Erlotibib 150mg Capsule, we follow the practice of brand innovator (Tarceva)(which is tablet) to perform the dissolution profile study, so we use the medium on 1%SLS IN 0.1N HCl. Meanwhile based on the FDA recommendations, Dissolution study is preferred in medium 0.1N HCl".
	3.2.P.5.2	Justification shall be submitted for variation in dissolution medium applied by firm i.e., 0.1NHCl + 1% SLS from that recommended by the US FDA i.e.0.01NHCl + 0.02% Tween 80.	Firm has attached a document regarding the use of 1% SLS IN 0.1N HCl in which principle states "We Actero Middle east Company hereby notify concerning the dissolution study Erlotibib 150mg Capsule, we follow the practice of brand innovator (Tarceva)(which is tablet) to perform the dissolution profile study, so we use the medium on 1%SLS IN 0.1N HCl. Meanwhile based on the FDA recommendations, Dissolution study is preferred in medium 0.1N HCl".
	3.2.P.8.3	Submit stability studies data of three batches till claimed shelf at long term stability conditions and at accelerated stability conditions for 6 months.	Firm has submitted a letter which principle states, "We hereto commit to stability results of the rest two batches will be prepared once the accelerated and long-term stabilities are performed".

Decision: Approved with innovator's specifications as per policy of inspection of manufacturer abroad with submission of fee for revision of specification i.e. 7500/-.
Registration letter shall be issued after the submission of the following data/ documents/clarification.

- **Clarification of name of Market Authorization Holder (abroad).**
- **Drug Substance specifications, analytical procedures, analytical method verification and batch analysis & COAs.**
- **Comparative Dissolution profile in three dissolution mediums.**
- **Submit stability studies data of three batches till claimed shelf at long term stability conditions and at accelerated stability conditions for 6 months.**

122.	Name, address of Applicant / Importer	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor

	Name and address of marketing authorization holder (abroad)	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial zone, Karaj, Iran.
	Name, address of manufacturer(s)	Actero Middle East, On the corner of 8th Golestan , Sarvestan Blvd., Baharestan Industrial zone Karaj Iran.
	Name of exporting country	Iran
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: ZSP-W6J-GMJR: 14-05-2024
	Details of fee submitted	PKR 300,000/-: 16-04-2024
	The proposed proprietary name / brand name	**Imatinib ACTe 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imatinib (as Mesylate) …….100mg
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	Any other
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 665/32553) issuance date 9-7-2022 issued by Food and Drug Administration, Ministry of Health and Medical Education, Iran. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement.
	The status in reference regulatory authorities	Gleevec 100mg film coated Tablet of Novartis. US FDA Approved.
	For generic drugs (me-too status)	Imatinib Norman 100mg Tablet of Merixil Pharma.
	Proposed pack size & MRP	As per SRO

Remarks of the Evaluator (XXIV):

Sr. #	Section	Observation	Firm's Response
1.	1.3	• Name and address of the Market authorization holder declared on submitted COPP is different form that mentioned in Sole Agency agreement. • Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant firm shall be submitted.	As per submitted Copy of LoA by the firm the name of the MAH is "Actero Middle East Pharmaceutical Company".
2.	1.5.6	Submitted specifications declared as "In house specifications" shall be justified with reference to the "Guidance Document Regarding Application of Drug Product Specifications" published vide letter "No. 9-2/2022-PEC.	Firm provided the following submission from the principle: "Our drug product Imatinib ACTe Tablet 100mg is not registered in any pharmacopeia, but the reference drug product Gleevec 100mg Tablet is USFDA Approved, as per the Guidance Document Regarding Application of Drug

			Product Specifications the product specification of our product is As per Innovator Specifications.
3.	3.2.P.2	Formulation development in section 3.2.P.2 has been submitted from M/s Hetero Labs. India Justification shall be submitted on this regard.	Firm has submitted formulation development data by the drug product manufacturer i.e. Actero Middle East, Iran.

Decision: Approved with innovator's specifications as per policy of inspection of manufacturer abroad with submission of fee for revision of specification i.e. 7500/-.

123.	Name, address of Applicant / Importer	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh, India.
	Name, address of manufacturer(s)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh-173205,India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: ZSP-W6J-GMJR: 19-04-2024
	Details of fee submitted	PKR 300,000/-: 02-02-2024
	The proposed proprietary name / brand name	**Zaxol 30mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Paclitaxel.....30mg Polyoxyl 35 Castor Oil USNF ..... 527mg Dehydrated alcohol BP..... 49.7%5v/v
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	USP Specifications
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. HFW-H (Drugs) 98/09(Vol.I)/23-12 valid upto 09-01-2025 issued by State Drugs Controller, India. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization/Exclusive Distributor Agreement from Zuvius Lifesciences PVT LTD, India in the name of Lab Diagnostic Systems (SMC) Pvt. Ltd. Rawalpindi.
	The status in reference regulatory authorities	Taxol by Bristol-Myers Squibb Company Princeton, NJ 08543 USA. US FDA Approved.
	For generic drugs (me-too status)	Paclitaxel Ebewe 30Mg/5ml Concentrate for Solution for Infusion.

		MAH: Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved as per policy of inspection of manufacturer abroad		
124.	Name, address of Applicant / Importer	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh, India.
	Name, address of manufacturer(s)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh-173205,India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: R7W-NU4-X3TA: 19-04-2024
	Details of fee submitted	PKR 300,000/-: 02-02-2024
	The proposed proprietary name / brand name	**Zaxol 100mg/16.7ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Paclitaxel.....100mg Polyoxyl 35 Castor Oil USNF ..... 527mg Dehydrated alcohol BP..... 49.7%5v/v
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	USP Specifications
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. HFW-H (Drugs) 98/09(Vol.I)/23-12 valid upto 09-01-2025 issued by State Drugs Controller, India. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization/Exclusive Distributor Agreement from Zuvius Lifesciences PVT LTD, India in the name of Lab Diagnostic Systems (SMC) Pvt. Ltd. Rawalpindi.
	The status in reference regulatory authorities	Taxol by Bristol-Myers Squibb Company Princeton, NJ 08543 USA—US FDA Approved.
	For generic drugs (me-too status)	Paclitaxel Ebewe 100Mg/16.7ml Concentrate for Solution for Infusion. MAH: Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	As per SRO
Evaluation by PEC (XXIV):		

Decision: Approved as per policy of inspection of manufacturer abroad		
125.	Name, address of Applicant / Importer	M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd., 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: N/A Validity: 04-08-2024. Status: License to Sell Drugs as Distributor
	Name and address of marketing authorization holder (abroad)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh, India.
	Name, address of manufacturer(s)	Zuvius Lifesciences Pvt. Ltd., .At.Kharuni-Lodhimajra Road,Vill.Nandpur, Baddi,Distt Solan, Himachal Pradesh-173205,India.
	Name of exporting country	India
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: R7W-NU4-X3TA: 19-04-2024
	Details of fee submitted	PKR 300,000/-: 02-02-2024
	The proposed proprietary name / brand name	**Zaxol 300mg/50ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Paclitaxel .....300mg Polyoxyl 35 Castor Oil USNF ..... 527mg Dehydrated alcohol BP..... 49.7%5v/v
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	USP Specifications
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. HFW-H (Drugs) 98/09(Vol.I)/23-12 valid upto 09-01-2025 issued by State Drugs Controller, India. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization/Exclusive Distributor Agreement from Zuvius Lifesciences PVT LTD, India in the name of Lab Diagnostic Systems (SMC) Pvt. Ltd. Rawalpindi.
	The status in reference regulatory authorities	Taxol by Bristol-Myers Squibb Company Princeton, NJ 08543 USA—US FDA Approved.
	For generic drugs (me-too status)	Paclitaxel Ebewe 300Mg/50ml Concentrate for Solution for Infusion. MAH: Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved as per policy of inspection of manufacturer abroad		
126.	Name, address of Applicant / Importer	Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.

	Details of Drug Sale License of importer	License No: 595 Address: Plot No. 37, Sector 19, Korangi Industrial Area Karachi. Address of Godown: N/A Validity: 16-06-2024. Status: License to Sell Drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Deva Holding A.Ş. Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece – İstanbul / TURKEY
	Name, address of manufacturer(s)	Deva Holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagec Mah., Faith Bulvari No:26 Kapakli/Tekirdag/Turkey.
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: PDR-UNY-LMMX: 04-03-2024
	Details of fee submitted	PKR 150,000/-: 20-11-2023 & PKR 150,000/-: 25-01-2024
	The proposed proprietary name / brand name	**Imatis 100mg Film Coated Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imatinib Mesylate 119.50mg equivalent to Imatinib …..100mg
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	Innovator's Specifications
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 2023/1082) valid up to 14-03-2025 issued by Turkish Medicines And Medical Devices Agency issued on 14-03-2023. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization/Sole Market Authorization from Deva Holding A.Ş. Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece – İstanbul / TURKEY with industrial address located at Deva Holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagec Mah., Faith Bulvari No:26 Kapakli/Tekirdag/Turkey in the name of Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	The status in reference regulatory authorities	Gleevec Novartis Pharmaceuticals Corporation East Hanover, New Jersey. US FDA Approvd.
	For generic drugs (me-too status)	Glivec 100mg Tablet of Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved as per policy of inspection of manufacturer abroad		

127.	Name, address of Applicant / Importer	Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	Details of Drug Sale License of importer	License No: 595 Address: Plot No. 37, Sector 19, Korangi Industrial Area Karachi. Address of Godown: N/A Validity: 16-06-2024. Status: License to Sell Drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Deva Holding A.Ş. Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece – İstanbul / TURKEY
	Name, address of manufacturer(s)	Deva Holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagec Mah., Faith Bulvari No:26 Kapakli/Tekirdag/Turkey.
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: TNU-657-NU1N: 04-03-2024
	Details of fee submitted	PKR 150,000/-: 20-11-2023 & PKR 150,000/-: 25-01-2024
	The proposed proprietary name / brand name	**Imatis 400mg Film Coated Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imatinib Mesylate 478mg equivalent to Imatinib …..400mg
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic
	Reference to Finished product specifications	Innovator's Specifications
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 2023/1083) valid up to 14-03-2025 issued by Turkish Medicines And Medical Devices Agency issued on 14-03-2023. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization/Sole Market Authorization from Deva Holding A.Ş. Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece – İstanbul / TURKEY with industrial address located at Deva Holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagec Mah., Faith Bulvari No:26 Kapakli/Tekirdag/Turkey in the name of Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	The status in reference regulatory authorities	Gleevec Novartis Pharmaceuticals Corporation East Hanover, New Jersey. US FDA Approved.
	For generic drugs (me-too status)	Glivec 400mg Tablet of Novartis Pharma (Pakistan) Limited.

	Proposed pack size & MRP	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved as per policy of inspection of manufacturer abroad		

128.	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Pvt) Limited, plot no. WH-26 & 27-A3 , Korangi Creek Industrial Park,, Karachi
	Name, address of Manufacturing site.	M/s Oncogen Pharma (Pvt) Limited, plot no. WH-26 & 27-A3 , Korangi Creek Industrial Park,, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 17A-5GV-ZN9X dated 17-05-2023
	Details of fee submitted	Rs.30,000/- dated 14-05-2024
	The proposed proprietary name / brand name	**Imatigliv Tablet 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Imatinib Mesylate equivalent to Imatinib…….400mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, BCR-ABL tyrosine kinase inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Glivec 400mg Tablet of M/s Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	3 x 10's. 100,000/-

Evaluation by PEC(XXIV):

Section#	Observation	Firm's response
1.6.5	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.	
3.2.S.4.4	➢ Submitted COA of drug substance form M/s Oncogen does not declare the batch no.	
3.2.S.5	➢ Source of working standard is different from the source of drug substance. Clarification shall be submitted in this regard.	
3.2.P.2.2.1	➢ Individual results for each unit shall be submitted in the CDP study report.	
3.2.P.8.3	➢ Reconciliation record of the imported quantity of Imatinib mesylate shall be submitted since submitted clearance certificate has been issued for Imatinib 100mg tablet. ➢ Stability data of 6th month time point shall be submitted.	

Decision: Deferred for submission of reply to above cited shortcomings.

Application Applied on Form 5F for Local Manufacturing
Routine Cases:

129.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.

	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30595 dated 30-10-2022
	Details of fee submitted	PKR 30,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …25mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Brivatam 25mg Film Coated tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore.
	Proposed pack size & MRP	As per SRO
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
130.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30584 dated 30-10-2022
	Details of fee submitted	PKR 30,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …50mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications

	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Brivatam 50mg Film Coated tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore.
	Proposed pack size & MRP	As per SRO
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
131.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30580 dated 30-10-2022
	Details of fee submitted	PKR 75,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …75mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Brivatam 75mg Film Coated tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore.
	Proposed pack size & MRP	As per SRO
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
132.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30585 dated 30-10-2022
	Details of fee submitted	PKR 30,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Brivaracetam …100mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Brivatam 100mg Film Coated tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore.
	Proposed pack size & MRP	As per SRO
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
133.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd., A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 30593 dated 30-10-2022
	Details of fee submitted	PKR 30,000/- dated 28-09-2022
	The proposed proprietary name / brand name	**Brivaracetam 10mg/ml Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Brivaracetam …10mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant/Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Brivatam 10mg/ml Oral Solution of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore.

	Proposed pack size & MRP	As per SRO
Remarks of Evaluator (XXIV):		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Agenda of Evaluator PEC-XXV

Case no.01 Registration applications of New DML (Veterinary)

a. New Cases

II. M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of DML by way of formulation with following section(s):

2. Liquid Injectable Section General (Vet.)

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied
Liquid Injectable Section General (Vet.)	51	10

Liquid Injectable Section General (Vet.) (51 Products/ 10 Molecules)		
134.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 1% Liquid Injection
	Composition	Each 100ml contains Ivermectin ……. 1g
	Tracking ID, date & fee	GZH-ASE-U3RY dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 0773396799)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	500ml; Decontrolled
	Me-too status	Mac Rold 1% Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 106818)
	GMP status	New License
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility i.e LVP Liquid Injectable Section General (Vet.).	
135.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 1% Liquid Injection
	Composition	Each 100ml contains Ivermectin ……. 1g
	Tracking ID, date & fee	AN6-NSY-3382 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 87612298)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	BP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Ivoron Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 112245)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
136.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 1% Liquid Injection
	Composition	Each 100ml contains Ivermectin ……. 1g
	Tracking ID, date & fee	JYM-EB2-XGHU dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 06884893170)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Ivoron Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 112248)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
137.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 1% Liquid Injection
	Composition	Each 100ml contains Ivermectin ……. 1g
	Tracking ID, date & fee	QJ3-9GJ-7AZE dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 76476866)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ivoron Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No.112244)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
138.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 2% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 20mg
	Tracking ID, date & fee	1WU-TZM-DAEZ dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 244827330957)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Ivermec 2% Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No. 111546)
	GMP status	New License

	Remarks of the Evaluator	
	Decision: Approved.	
139.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 2% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 20mg
	Tracking ID, date & fee	SEB-APU-ZTPY dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 8594713834)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Ivermec 2% Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No. 111547)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
140.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 2% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 20mg
	Tracking ID, date & fee	G39-3GL-4DUD dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 9519001219)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Micrise-2% Injection of M/s Biorise Pharmaceuticals, Multan (Reg. No. 111205)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
141.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 3.15% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 31.5mg
	Tracking ID, date & fee	D8E-DHW-855U dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 566777603)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Vectin 3.15% Injection of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 112157)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
142.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	AR EVOMEC 3.15% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 31.5mg
	Tracking ID, date & fee	H7Q-SXT-9WNW dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 6901754351)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Vectin 3.15% Injection of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 112158)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
143.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR EVOMEC 3.15% Liquid Injection
	Composition	Each ml contains Ivermectin ……. 31.5mg
	Tracking ID, date & fee	YS4-951-U16P dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 6399728882)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Vectin 3.15% Injection of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 112159)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
144.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 10% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 100mg
	Tracking ID, date & fee	6A2-8ND-D7ZV dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 6306069378)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Enflox-10% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112210)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
145.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 10% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 100mg

	Tracking ID, date & fee	ZJP-8AB-LHUG dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 98189134)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Enflox-10% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
146.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 10% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 100mg
	Tracking ID, date & fee	6D6-XSR-R9A8 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 071984572)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Enflox-10% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112213)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
147.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 20% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 200mg
	Tracking ID, date & fee	T2P-TL1-S8N7 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 57481343)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Enflox-20% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.112214)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
148.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 20% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 200mg
	Tracking ID, date & fee	81H-9R9-AV8S dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 82418893932)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications

	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Enflox-20% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.112216)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
149.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ENRO 20% Liquid Injection
	Composition	Each ml contains: Enrofloxacin ……. 200mg
	Tracking ID, date & fee	GE3-RM4-H2SD dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 312370505)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Enflox-20% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.112217)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
150.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-50 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 50mg
	Tracking ID, date & fee	23B-5LY-SY6N dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 17968593397)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Floonix Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112246)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
151.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-50 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 50mg
	Tracking ID, date & fee	G7J-AP4-T8H6 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 0636905181)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Floonix Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112247)
	GMP status	New License
	Remarks of the Evaluator	

	Decision: Approved.	
152.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-50 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 50mg
	Tracking ID, date & fee	TJE-B8E-XZLS dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 63386940)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Floonix Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112255)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
153.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-83 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 83mg
	Tracking ID, date & fee	1QN-8Y7-ETAB dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 582362501425)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Harry Mine 8.83 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.109030)
	GMP status	New License
	Remarks of the Evaluator	**Shortcomings:** The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
154.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-83 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 83mg
	Tracking ID, date & fee	VA6-TM7-LU5V dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 4846972090)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled

	Me-too status	Harry Mine 8.83 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.109031)
	GMP status	New License
	Remarks of the Evaluator	**Shortcomings:** The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
155.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR FLUXIN-83 Liquid Injection
	Composition	Each ml contains: Flunixin as Meglumin ……. 83mg
	Tracking ID, date & fee	A17-Y65-N29H dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 730148484)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Harry Mine 8.83 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.109032)
	GMP status	New License
	Remarks of the Evaluator	**Shortcomings:** The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
156.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR GENTA TYLO 50 Liquid Injection
	Composition	Each ml contains: Gentamicin as Sulphate ……. 50mg Tylosin as Tartrate……. 100mg
	Tracking ID, date & fee	65G-EY8-V881 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 27490970)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Tylogent Injection (**50ml**) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
157.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	AR GENTA TYLO 50 Liquid Injection
	Composition	Each ml contains: Gentamicin as Sulphate ……. 50mg Tylosin as Tartrate……. 100mg
	Tracking ID, date & fee	VHS-4RT-NM65 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 65125122636)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Tylogent Injection (50ml) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
158.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR GENTA TYLO 50 Liquid Injection
	Composition	Each ml contains: Gentamicin as Sulphate ……. 50mg Tylosin as Tartrate……. 100mg
	Tracking ID, date & fee	1X5-R8X-WU6W dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 146825386)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Tylogent Injection (50ml) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
159.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR GENTA TYLO 100 Liquid Injection
	Composition	Each ml contains: Gentamicin as Sulphate ……. 100mg Tylosin as Tartrate……. 50mg
	Tracking ID, date & fee	ELX-2US-4L7Q dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 142946900787)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Gemsin Injection of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111551)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
160.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR GENTA TYLO 100 Liquid Injection

	Composition	Each ml contains: Gentamicin as Sulphate ……. 100mg Tylosin as Tartrate……. 50mg
	Tracking ID, date & fee	B5P-BRW-3HTR dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 646703750681)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Gemsin Injection of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111552)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
161.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ADE 20 Liquid Injection
	Composition	Each ml contains: Vitamin A …… 80,000 IU Vitamin D3……40,000 IU Vitamin E…… 20mg
	Tracking ID, date & fee	64V-63Z-ZT27 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 5586316999)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	3-Vitz Injection of M/s Epoch Pharmaceuticals, Karachi. (Reg. No. 069614)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
162.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ADE 20 Liquid Injection
	Composition	Each ml contains: Vitamin A …… 80,000 IU Vitamin D3……40,000 IU Vitamin E…… 20mg
	Tracking ID, date & fee	EWJ-B13-W71Z dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 6249777565)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	3-Vitz Injection of M/s Epoch Pharmaceuticals, Karachi. (Reg. No. 069614)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
163.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ADE 20 Liquid Injection

	Composition	Each ml contains: Vitamin A …… 80,000 IU Vitamin D3……40,000 IU Vitamin E…… 20mg
	Tracking ID, date & fee	GPE-3GM-X2TX dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 437550557)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	3-Vitz Injection of M/s Epoch Pharmaceuticals, Karachi. (Reg. No. 069614)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
164.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ADE 40 Liquid Injection
	Composition	Each ml contains: Vitamin A …… 100,000 IU Vitamin D3……40,000 IU Vitamin E…… 40mg
	Tracking ID, date & fee	J8Q-24Z-SGXX dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 2848227027)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	ADEKA Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
165.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR ADE 40 Liquid Injection
	Composition	Each ml contains: Vitamin A …… 100,000 IU Vitamin D3……40,000 IU Vitamin E…… 40mg
	Tracking ID, date & fee	5RB-ENJ-YJME dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 35838176)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	ADEKA Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
166.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	AR ADE 40 Liquid Injection
	Composition	Each ml contains: Vitamin A …… 100,000 IU Vitamin D3……40,000 IU Vitamin E…… 40mg
	Tracking ID, date & fee	DJY-T8Y-ZZ69 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 92751281992)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	ADEKA Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
167.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MEPRA 50 Liquid Injection
	Composition	Each ml contains: Mepyramine Maleate.……. 50mg
	Tracking ID, date & fee	45H-VSN-XNUA dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 8999094477)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Mepylina Injection of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 049682)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
168.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MEPRA 50 Liquid Injection
	Composition	Each ml contains: Mepyramine Maleate.……. 50mg
	Tracking ID, date & fee	ZGB-QUN-5GU5 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 51487038451)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Mepylina Injection of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 049682)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
169.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MEPRA 50 Liquid Injection
	Composition	Each ml contains:

		Mepyramine Maleate……. 50mg
	Tracking ID, date & fee	72V-BQQ-NYQW dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 87581820646)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Mepylina Injection of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 049682)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
170.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	TROPIN Liquid Injection
	Composition	Each ml contains: Atropine Sulphate …… 1mg
	Tracking ID, date & fee	QG5-A2G-8NST dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 8083369614)
	Pharmacological Group	Anti-cholinergic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Atro-Kak Injection of M/s Kakasian Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 039982)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
171.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	TROPIN Liquid Injection
	Composition	Each ml contains: Atropine Sulphate …… 1mg
	Tracking ID, date & fee	S8E-L64-H6YW dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 06554853999)
	Pharmacological Group	Anti-cholinergic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Atro-Kak Injection of M/s Kakasian Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 039982)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
172.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	TROPIN Liquid Injection
	Composition	Each ml contains: Atropine Sulphate …… 1mg
	Tracking ID, date & fee	LGL-SY1-Y51V dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 14246885646)
	Pharmacological Group	Anti-cholinergic
	Type of Form	Form 5

	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Atro-Kak Injection of M/s Kakasian Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 039982)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
173.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 3 Liquid Injection
	Composition	Each ml contains: Ivermectin ……. 20mg Clorsulon ……. 10mg
	Tracking ID, date & fee	ENT-87J-MUM3 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 54435717)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Harry Sulon 20 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109026)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
174.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 30 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 20mg Clorsulon ……. 10mg
	Tracking ID, date & fee	7LV-82M-2741 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 1960786792)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Harry Sulon Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109023)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
175.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 30 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 20mg Clorsulon ……. 10mg
	Tracking ID, date & fee	141-Z64-R8YV dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 7147956892)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Harry Sulon Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109024)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
176.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 30 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 20mg Clorsulon ….……. 10mg
	Tracking ID, date & fee	5XS-9Z4-SE5L dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 9080414065)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Harry Sulon Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109025)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
177.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 110 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 1g Clorsulon.……. 10g
	Tracking ID, date & fee	QZ8-W11-DZH5 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 132526099657)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Clortin Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 113567)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
178.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 110 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 1g Clorsulon.……. 10g
	Tracking ID, date & fee	TB4-3SH-3RV4 dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 6631723539)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Clortin Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 113569)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
179.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CLOMEC 110 Liquid Injection
	Composition	Each 100ml contains: Ivermectin ……. 1g Clorsulon.……. 10g
	Tracking ID, date & fee	7SH-PJT-68WH dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 0273671577)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Clortin Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 113570)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
180.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MARFLOX Liquid Injection
	Composition	Each ml contains: Marbofloxacin ……. 100mg
	Tracking ID, date & fee	BA7-Z87-TJYH dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 5660362445)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Marbo-Vetz 10% Injection of M/s Vetz Pharmaceuticals (Pvt.) Ltd., Kotri Sindh. (Reg. No. 099430)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
181.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MARFLOX Liquid Injection
	Composition	Each ml contains: Marbofloxacin ……. 100mg
	Tracking ID, date & fee	Z6S-8HG-Q97G dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 873605211744)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Marbo-Vetz 10% Injection of M/s Vetz Pharmaceuticals (Pvt.) Ltd., Kotri Sindh. (Reg. No. 099431)

	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
182.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	MARFLOX Liquid Injection
	Composition	Each ml contains: Marbofloxacin ……. 100mg
	Tracking ID, date & fee	VQD-TW7-VUZW dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 614098663214)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Marbo-Vetz 10% Injection of M/s Vetz Pharmaceuticals (Pvt.) Ltd., Kotri Sindh. (Reg. No. 099432)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
183.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR AVIL Liquid Injection
	Composition	Each ml contains: Pheniramine Maleate ……. 25mg
	Tracking ID, date & fee	A8P-SZS-QZ7S dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 4691975610)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Rexavil Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi. (Reg. No. 028598)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
184.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	AR AVIL Liquid Injection
	Composition	Each ml contains: Pheniramine Maleate ……. 25mg
	Tracking ID, date & fee	UN7-U99-7GSZ dated 31-05-2024 Rs 30,000/- dated 16-05-2024 (Slip No. 96289046758)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Rexavil Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi. (Reg. No. 028598)
	GMP status	New License
	Remarks of the Evaluator	
	Decision: Approved.	
III.	**M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.**	

CLB in its 296th meeting held on 02nd April, 2024 has considered and approved the grant of DML by way of formulation with following section(s):

1. Sachet/Granules (General) Section Vet.

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied
Sachet/Granules (General) Section Vet.	5	5

Sachet/Granules (General) Section Vet.
(5 Products/ 5 Molecules)

185.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.
	Brand Name +Dosage Form + Strength	De Cure Oral Powder
	Composition	Each 12gm contains: Neomycin Sulphate .....400mg Streptomycin Sulphate .....400mg Sulphaguanidine .....4gm Kaolin.....4gm Pectin .....400mg Bismuth Subnitrate .....2gm Vitamin A Acetate.....80000IU
	Tracking ID, date & fee	YDW-HNN-Q6JD dated 13-05-2024 Rs 30,000/- dated 08-05-2024 (Slip No. 342953197)
	Pharmacological Group	Antibacterial and Anti-diarrheal
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	12gm, 50gm, 100gm; Decontrolled
	Me-too status	Vendiarol Oral Powder of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111365)
	GMP status	New License
	Remarks of the Evaluator	**Target Species:** Lambs
	Decision: Approved.	
186.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Alba One 20% Oral Powder
	Composition	Each gram contains: Albendazole.....200mg
	Tracking ID, date & fee	BG3-QPW-353W dated 13-05-2024 Rs 30,000/- dated 08-05-2024 (Slip No. 691397766457)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	5gm, 10gm, 20gm, 50gm, 100gm; Decontrolled
	Me-too status	Uni Babenzin Granules of M/s Atzan Pharmaceuticals, Sargodha. (Reg. No. 094482)
	GMP status	New License
	Remarks of the Evaluator	**Target Species:** Cattle and Sheep
	Decision: Approved.	
187.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.

	Brand Name +Dosage Form + Strength	Metabolar Oral Powder
	Composition	Each Kg contains: Vitamin A.....15,000, 000IU Vitamin D3.....300, 0000 IU Vitamin E .....6000mg Vitamin K3.....4000mg Vitamin B1.....5000mg Vitamin B2.....6000mg Vitamin B6.....4000mg Vitamin B12.....9000mcg Vitamin C.....15000mg Folic Acid.....750mg Nicotine Acid.....25,000mg Calcium Pantothenate.....10,000mg
	Tracking ID, date & fee	84J-E6M-ZAT5 dated 13-05-2024 Rs 30,000/- dated 09-05-2024 (Slip No. 710087460)
	Pharmacological Group	Restorative/ Nutritional Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10gm, 20gm, 50gm, 100gm; Decontrolled
	Me-too status	Symostress Water Soluble Powder of M/s Symans Pharmaceutical Lahore (Reg. No. 014133)
	GMP status	New License
	Remarks of the Evaluator	**Target Species:** Horse, Camels, Cattle, Sheep, Goats and Rabbits and Poultry
	Decision: Approved.	
188.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.
	Brand Name +Dosage Form + Strength	One Digester Oral Powder
	Composition	Each Kg contains: Propionic Acid Calcium .....250gm Propionic Sodium Acid .....400gm Acetanilide.....150gm Magnesium Oxide .....125gm Iron Sulphate.....400mg Sodium Molybdate .....100mg Zinc Sulphate .....100mg Magnesium Sulphate.....200mg Copper Sulphate .....450mg Cobalt Sulphate.....400mg Sodium Chloride.....20g
	Tracking ID, date & fee	3W5-41D-11SY dated 16-05-2024 Rs 30,000/- dated 13-05-2024 (Slip No. 10499301720)
	Pharmacological Group	Digestive Tonic/ Digestive Stimulant
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10gm, 20gm, 50gm, 100gm; Decontrolled
	Me-too status	Gest Oral Powder of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111366)
	GMP status	New License
	Remarks of the Evaluator	**Target Species:** Cattle, Sheep and Goats. **Shortcomings:**

		The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs.30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
189.	Name and address of manufacturer / Applicant	M/s One Health Pharma, Plot# 28/2-A, SITE Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Cozole Oral Powder
	Composition	Each gram contains: Trimethoprim .....80mg Sulfadiazine 400mg
	Tracking ID, date & fee	6PD-7Q9-U524 dated 13-05-2024 Rs 30,000/- dated 08-05-2024 (Slip No. 43224893)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet Specifications
	Pack size & Demanded	5gm, 10gm, 20gm, 50gm, 100gm; Decontrolled
	Me-too status	Cotrim 50 Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043295) Trisulf Powder of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. (Reg. No.109093) Could not be confirmed in the applied strength
	GMP status	New License
	Remarks of the Evaluator	**Target Species:** Cattle, Sheep, and Chickens Cubarmix 48%, 80 mg/g and 400 mg/g powder for oral administration for calves (**approved in the Netherlands**)
	Decision: Approved.	

b. Deferred cases:

190.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Furosmed Oral Powder
	Composition	Each Kg contains: Furosemide.....20gm Sodium Chloride .....35gm Potassium Chloride.....400mg Magnesium Chloride.....35gm Calcium Carbonate.....45gm Manganese Sulphate ..... 1 gm
	Tracking ID, date & fee	VRS-ZJQ-QEYP dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 0131673939)
	Pharmacological Group	Flusher
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Neyphralyte Powder of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071072)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, cattle **Shortcomings:**

		➢ Clarification regarding applied formulation is required since **Magnesium chloride** is mentioned in composition on form-5 while **Magnesium sulphate** is mentioned in master formula. Accordingly, provide evidence of applied formulation already approved by DRAP (generic/me-too) alongwith registration number, brand name and name of the firm, ➢ Submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision of 335th meeting: Deferred for following: • Clarification regarding applied formulation since Magnesium chloride is mentioned in composition on form-5 while Magnesium sulphate is mentioned in master formula. Accordingly, provide evidence of applied formulation already approved by DRAP (generic/me-too) alongwith registration number, brand name and name of the firm, • Rs.7500/- for correction in finished product specifications before issuance of registration letter.	
	Updated status: The firm has submitted that in our applied product AR Furosmed Oral Powder it is a typographical error **Magnesium Chloride is mistakenly written instead of Magnesium Sulphate.** **Mee Too Status**: Composition of the product is same as per me too reference product Product Name: "Nephralyte Powder" Manufactured by: Selmore Pharmaceutical Pvt. Ltd. Reg. No. 071072. Composition shared here for the reference purpose Each Kg contains: Furosemide ------ 20 gm Sodium Chloride ----- 35 gm Potassium Chloride ---- 400 mg Magnesium Sulphate ------ 35 gm Calcium Carbonate ------- 45 gm Manganese Sulphate …….. 1 gm The firm has submitted fee Rs. 7500/- vide slip No. 90529181 for correction in finished product specifications. **Shortcomings:** Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
	Decision: Approved with following label claim: **Each Kg contains:** **Furosemide ------ 20gm** **Sodium Chloride ----- 35gm** **Potassium Chloride ---- 400mg** **Magnesium Sulphate ------ 35gm** **Calcium Carbonate ------- 45gm** **Manganese Sulphate …….. 1gm** **Firm shall submit differential fee Rs. 22,500/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	

Case no. 02 Registration applications of import cases

a. Deferred Cases (Veterinary)

191.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020.

		Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32615 Dated 08-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 08-12-2020
	Brand Name +Dosage Form + Strength	Permethrin Pharma Insecticide Shampoo
	Composition	Each 100ml contains: Permethrin…1g
	Finished Product Specification	Inhouse
	Pharmacological Group	Pyrethrines
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Updated status: The firm has submitted the following: • copy of DSL valid till **07-11-2027** • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Link for verification of approval status of Permethrin Pharma in EU; **authorized in Bulgaria** (https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=permethrin)	
	Decision: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country.	

192.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24241 Dated 17-09-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-09-2020
	Brand Name +Dosage Form + Strength	Gentamast F-Intramammary Suspension
	Composition	Each Gram Contains: Gentamicin Sulphate…10,000 IU (0.0167gm)
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	10gm
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Updated status: The firm has submitted the following: • copy of DSL valid till **07-11-2027**	

	• Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Link for verification of approval status of Gentamast F-Intramammary Suspension in EU; **authorized in Bulgaria** (https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=gentamast)	
	Decision: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country.	
193.	Name and address of Applicant	M/s. Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of Drug Sale License	Address: Commercial Area, Aziz Bhatti Town, District Sargodha Validity: 20/11/2019 Status: Licence to sell as a ―Distributer‖
	Name and address of manufacturer	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name and address of marketing authorization holder	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name of exporting country	The People‘s Republic Of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.24485 Dated 14/12/2017
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Oxydong LA -20 Injection
	Composition	Each 100ml contains: Oxytetracycline…. 20g
	Target Species	--------
	Finished Product Specification	Manufacturer’s Specifications
	Pharmacological Group	Antibiotic
	Shelf life	24months
	Demanded Price	De-Controlled
	Pack size	100ml
	International availability	Could not be confirmed
	Detail of certificates attached	**LEGALIZED CERTIFICATE OF FREE SALES:** Certificate No. No Number Certified by: Shandong Animal Husbandry & Veterinary Bureau. Issued date: 27/09/2017 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: **Legalized copy of Letter of authorization** Huzaifa International & Shandong Soocom Animal remedy Co., Ltd. For following products: Oxytetracycline Injection 20 % (Oxydong-20) Enrofloxacin Oral Solution 20% (Enrodong-20) Oxytetracycline Injection 5 % (Oxydong-5) Validity:

	➢ Remarks of the Evaluator		
	Sr. No.	**Remarks of the Evaluator.**	**Reply of the Firm.**
	1	In case of finished product label, the Urdu version of Name of drug, dosage & instructions as per requirement of (Drugs labeling and prescribing rules) 1986 is required while you have not submitted the Urdu version of dosage.	Applicant has submitted Urdu version of Name of drug, dosage & instructions.
	2	Submit evidence of Shandong Animal Husbandry & Veterinary Bureau as a concerned regulatory body of M/s. Shandong Soocom Animal Remedy.	-------
	3	Submit stability studies both accelerated & real time of three batches of applied drug product conducted in accordance with zone IV-A conditions.	Stability of three batches of applied drug product both accelerated & real time conducted in accordance with zone IV-A condition for 24 months is submitted by the firm. (Data is same to that of 25°C ±2°C, RH 65%±5%)
	4	Justification/Clarification on scientific basis for not carrying out endotoxin test of applied formulation.	According to international pharmacopoeia endotoxin test is only required to be performed for intravenous injections or powders for injections. Our applied drug product is oil based injection which is injection intramuscularly or subcutaneously, therefore endotoxin test does not require to be performed. **However applied drug product is water based injection as per data submitted in dossier.*
	5	Mention the type of primary packaging material weather it is type I, Type II, Or Type III glass container.	Type I glass Container.
	6	Submit copy of valid DSL of the applicant.	Copy of DSL submitted by the firm having following information on it. **Address:** Commercial Area, Aziz Bhatti Town, District Sargodha **Validity:** 20/11/2019 **Status:** Licence to sell as a "Distributer"
	Decision of 289th meeting: Deferred for submission of complete original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data sheets confirming conduction of stability studies of applied formulation as per Zone IVA conditions.		
	Updated status: The firm has submitted reply dated 12-09-2023 wherein stability studies data both accelerated & real time for three batches supported by laboratory reports, and raw data sheets are submitted in **Chinese language.**		
	Decision: Deferred for following: • **certified translated original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data sheets confirming conduction of stability studies of applied formulation as per zone IV-A conditions.** • **original valid letter of authorization** • **copy of valid DSL**		
194.	Name and address of Applicant	M/s. Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha.	
	Detail of Drug Sale License	Address: Commercial Area, Aziz Bhatti Town, District Sargodha	

		Validity: 20/11/2019 Status: Licence to sell as a ―Distributer‖
	Name and address of manufacturer	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name and address of marketing authorization holder	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name of exporting country	The People‘s Republic Of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.24484 Dated 14/12/2017
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Oxydong -5 Injection
	Composition	Each 100ml contains: Oxytetracycline…. 5g
	Target Species	--------
	Finished Product Specification	Manufacturer’s Specifications
	Pharmacological Group	Antibiotic
	Shelf life	24months
	Demanded Price	De-Controlled
	Pack size	100ml
	International availability	Could not be confirmed
	Detail of certificates attached	**LEGALIZED CERTIFICATE OF FREE SALES:** Certificate No. No Number Certified by: Shandong Animal Husbandry & Veterinary Bureau. Issued date: 27/09/2017 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: **Legalized copy of Letter of authorization** Huzaifa International & Shandong Soocom Animal remedy Co., Ltd. For following products: Oxytetracycline Injection 20 % (Oxydong-20) Enrofloxacin Oral Solution 20% (Enrodong-20) Oxytetracycline Injection 5 % (Oxydong-5) ➢ **Validity**:

➢ Remarks of the Evaluator

Sr. No.	Remarks of the Evaluator.	Reply of the Firm.
1	In case of finished product label, the Urdu version of Name of drug, dosage & instructions as per requirement of (Drugs labeling and prescribing rules) 1986 is required while you have not submitted the Urdu version of dosage.	Applicant has submitted Urdu version of Name of drug, dosage & instructions.
2	Submit evidence of Shandong Animal Husbandry & Veterinary Bureau as a concerned regulatory body of M/s. Shandong Soocom Animal Remedy.	-------
3	Submit stability studies both accelerated & real time of three batches of applied drug product conducted in accordance with zone IV-A conditions.	Stability of three batches of applied drug product both accelerated & real time conducted in accordance with zone IV-A condition for 24 months is submitted by the firm. (Data is same to that of 25°C ±2°C, RH 65%±5%)
4	Justification/Clarification on scientific basis for not carrying out endotoxin test of applied formulation.	According to international pharmacopoeia endotoxin test is only required to be performed for intravenous injections or powders for injections. Our applied drug product is oil based injection which is injection intramuscularly or subcutaneously, therefore endotoxin test does not require to be performed. **However applied drug product is water based injection as per data submitted in dossier.*
5	Mention the type of primary packaging material weather it is type I, Type II, Or Type III glass container.	Type I glass Container.

Decision of 289th meeting:
Deferred for submission of complete original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data sheets confirming conduction of stability studies of applied formulation as per Zone IVA conditions.

Updated status: The firm has submitted reply dated 12-09-2023 wherein stability studies data both accelerated & real time for three batches supported by laboratory reports, and raw data sheets are submitted in **Chinese language.**

Decision: Decision: Deferred for following:

- **certified translated original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data sheets confirming conduction of stability studies of applied formulation as per zone IV-A conditions.**
- **original valid letter of authorization since details regarding its date of issuance and validity could not be confirmed from the minutes.**
- **copy of valid DSL**

Agenda of Deputy Director (PE&R) (Mr. Muneeb Ahmed Cheema)

New Molecule:

195.	**Name, address of Applicant / Importer**	AstraZeneca Pharmaceuticals Pakistan Private Limited, C-50, Block-2, Clifton, Karachi Pakistan
	Details of Drug Sale License of importer	**License No:** DHODSK (Drug)/-139 License No. (290) dated 04.05.2023. **Address:** C-50, Block-2, Clifton, Karachi Pakistan **Address of Godown:** Plot No. 208/1, Sector 23 Korangi Industrial Area Karachi. **Validity:** 19.04.2028 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	AstraZeneca AB, SE-151 85 Sodertalje, Sweden
	Name, address of manufacturer(s)	AbbVie Limited, Carretera 2 KM 58.0 Cruce Davilia Barceloneta, PR 00617 Puerto Rico USA
	Name of exporting country	Sweden
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP issued by EMA vide No. 01/23/008919 dated 23.08.2023 indicates the product is licensed and available for sale.
	Details of letter of authorization / sole agency agreement	Letter of authorization by AstraZeneca AB, SE-151 85 Sodertalje, Sweden in name of AstraZeneca Pharmaceuticals Pakistan Private Limited, C-50, Block-2, Clifton, Karachi Pakistan dated 07.09.2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	34U-5YZ-NAE6 dated 13.03.2024
	Details of fee submitted	75000/- dated 05.12.2023 225000/- dated 18.01.2024
	The proposed proprietary name / brand name	LYNPARZA (Olaparib) 150mg film-coated tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olaparib……150mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic Drug: (Ovarian Cancer, Breast Cancer, Pancreatic Cancer & Prostate Cancer)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	56's

	Proposed unit price	Will be submitted later on to the Pricing Division
	The status in reference regulatory authorities	EMA, USFDA
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Lonza AG Lonzastrasse CH-3930 Visp Switzerland Dottikon Exclusive Synthesis AG Hembrunnstrasse 17 CH-5605 Dottikon Switzerland
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 60 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months and 6 months at 50°C/ ambient humidity.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Blister pack (The blister pack is made from a base web of aluminium laminate and sealed to a hard temper aluminium foil coated with heat seal lacquer. The blister cavities are formed during a cold-forming process)

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 36 months (03 years)
196.	**Name, address of Applicant / Importer**	AstraZeneca Pharmaceuticals Pakistan Private Limited, C-50, Block-2, Clifton, Karachi Pakistan
	Details of Drug Sale License of importer	**License No:** DHODSK (Drug)/-139 License No. (290) dated 04.05.2023. **Address:** C-50, Block-2, Clifton, Karachi Pakistan **Address of Godown:** Plot No. 208/1, Sector 23 Korangi Industrial Area Karachi. **Validity:** 19.04.2028 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	AstraZeneca AB, SE-151 85 Sodertalje, Sweden
	Name, address of manufacturer(s)	AbbVie Limited, Carretera 2 KM 58.0 Cruce Davilia Barceloneta, PR 00617 Puerto Rico USA.
	Name, address of batch release site	AstraZeneca AB, SE-151 85 Södertälje, Sweden
	Name of exporting country	Sweden
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP issued by EMA vide No. 01/23/008918 dated 23.08.2023 indicates the product is licensed and available for sale.
	Details of letter of authorization / sole agency agreement	Letter of authorization by AstraZeneca AB, SE-151 85 Sodertalje, Sweden in name of AstraZeneca Pharmaceuticals Pakistan Private Limited, C-50, Block-2, Clifton, Karachi Pakistan dated 07.09.2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	SPV-8ZB-6X5U dated 13.03.2024
	Details of fee submitted	75000/- dated 05.12.2023 225000/- dated 18.01.2024
	The proposed proprietary name / brand name	LYNPARZA (Olaparib) 100 mg film-coated tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olaparib……100mg
	Pharmaceutical form of applied drug	Film Coated Tablet

	Pharmacotherapeutic Group of (API)	Anti-Neoplastic Drug: (Ovarian Cancer, Breast Cancer, Pancreatic Cancer & Prostate Cancer)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	56's
	Proposed unit price	Will be submitted later on to the Pricing Division
	The status in reference regulatory authorities	EMA, USFDA
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Lonza AG Lonzastrasse CH-3930 Visp Switzerland Dottikon Exclusive Synthesis AG Hembrunnstrasse 17 CH-5605 Dottikon Switzerland
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 60 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months and 6 months at 50°C/ ambient humidity.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Blister pack

		(The blister pack is made from a base web of aluminium laminate and sealed to a hard temper aluminium foil coated with heat seal lacquer. The blister cavities are formed during a cold-forming process)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 36 months (03 years)
Evaluation by PEC:		
Decision: Approved with innovator's specifications.		

Agenda of Deputy Director (PEC) (Mr. Salateen Waseem Philip)

Item No. 01: New License / Section

197.	**Central Licensing Board in its 290th meeting held on 28th April 2023 approved the grant of DML # 000973 (Formulation) for the manufacturing facility of drug products as under: -** **i. Eye ointment (General)** **ii. Liquid injectable vial SVP (General)** **iii. Eye/Ear Drops (General)** **iv. Liquid Ampoule (General)**	
	Name, address of Applicant / Marketing Authorization Holder	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Name, address of Manufacturing site.	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: 4EE-VSP-65N1 Dated: 31-10-2022
	Details of fee submitted	PKR 30,000/-: 22-01-2024 (Slip # 72087693443)
	The proposed proprietary name / brand name	Linkat Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule contains: Lincomycin Hydrochloride equivalent to Lincomycin USP …….600mg
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	TGA Australia approved formulation.
	For generic drugs (me-too status)	Lincolcin Injection by Pfizer
	Proposed Pack size	2ml x 10's, 2ml x 50's (2 ml glass ampoule USP type-I)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation.
	For generic drugs (me-too status)	Lincolcin Injection by Pfizer

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country OF origin and should be valid till date.	Submitted
3.2.S.7	Please submit stability data of API as per climatic condition of Pakistan (Zone IV -A)	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

198.	**Name, address of Applicant / Marketing Authorization Holder**	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Name, address of Manufacturing site.	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: RP4-DVQ-5BSV Dated: 31-05-2024
	Details of fee submitted	PKR 30,000/-: 28-02-2024 (Slip # 699055734013)
	The proposed proprietary name / brand name	Drota Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule contains: Drotaverine Hydrochloride……..……40mg
	Pharmacotherapeutic Group of (API)	ANTIINFECTIVES FOR SYSTEMIC USE
	Reference to Finished product specifications	Innovator Specification

Evaluation by DD-PE&R:

Section	Observations	Status
1.5.8	The reference of approval of No-Spa injection in Hungary is not traceable on website of regulatory authority of Germany. Please submit evidence.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

199.	**Name, address of Applicant / Marketing Authorization Holder**	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Name, address of Manufacturing site.	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: JRB-73Z-7MHY Dated: 31-05-2024
	Details of fee submitted	PKR 30,000/-: 14-03-2024 (Slip # 559015896183)

	The proposed proprietary name / brand name	Ofloxin Eye Drop
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml contains: Ofloxacin USP ……3mg (0.3% w/v)
	Pharmacotherapeutic Group of (API)	ANTIINFECTIVES
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	OCUFLOX® USFDA approved formulation
	For generic drugs (me-too status)	Oflexer by Schazoo
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
200.	**Name, address of Applicant / Marketing Authorization Holder**	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Name, address of Manufacturing site.	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: QJH-7NZ-3TUJ Dated: 31-05-2024
	Details of fee submitted	PKR 30,000/-: 15-12-2023 (Slip # 48840994)
	The proposed proprietary name / brand name	Tobracin Eye Drop
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml contains: Tobramycin USP ……3mg (0.3% w/v)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Tobrex Eye drop by Novartis
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

201.	**Name, address of Applicant / Marketing Authorization Holder**	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Name, address of Manufacturing site.	**Al Barkat Pharmaceutical Industries (DML # 000973) Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: YJG-S41-3VL4 Dated: 31-05-2024
	Details of fee submitted	PKR 30,000/-: 28-02-2024 (Slip # 66535827)
	The proposed proprietary name / brand name	Dexacat Eye Drop
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml contains: Dexamethasone USP ……1mg (0.1% w/v)
	Pharmacotherapeutic Group of (API)	Anti-inflammatory Agents, ATC Code S01B A01.
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Maidex Eye drop by Novartis

Evaluation by DD-PE&R:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

202.	**Central Licensing Board in its 292nd meeting held on 04th October 2023 approved the grant of DML # 000985 (Formulation) including the manufacturing facility of "General Liquid Injectable ampoule / vials"**	
	Name, address of Applicant / Marketing Authorization Holder	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: L19-5LB-BWQX Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 23-04-2024 (Slip # 1895232477)
	The proposed proprietary name / brand name	Vonosaq 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: (iron(III)- hydroxide sucrose complex) Elemental iron (as Iron Sucrose)….100mg
	Pharmacotherapeutic Group of (API)	Haematinic

	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	A product of elite pharma
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
203.	**Name, address of Applicant / Marketing Authorization Holder**	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: R5A-ZQ4-1M6J Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 14-05-2024 (Slip # 69331315401)
	The proposed proprietary name / brand name	Levosaq Infusion (500mg/100ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial Contains: Levofloxacin as Hemihydrate ……. 500mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibacterial.
	Reference to Finished product specifications	JP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Leflox by Getz
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
204.	**Name, address of Applicant / Marketing Authorization Holder**	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: 6NJ-3UU-5XHM Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 14-05-2024 (Slip # 97975529)

	The proposed proprietary name / brand name	Ketosaq injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml vial Contains: Ketorolac Tromethamine ……. 30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Toradol injection by Martin Dow
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
205.	**Name, address of Applicant / Marketing Authorization Holder**	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd. (DML # 000985) Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC)**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: YNJ-BUG-6HSL Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 22-05-2024 (Slip # 676671164741)
	The proposed proprietary name / brand name	Metamol Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial Contains: Paracetamol ……... 1000mg
	Pharmacotherapeutic Group of (API)	Analgesic / antipyretic
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Provas by Sami Pharma
Evaluation by DD-PE&R:		
Decision: Approved with Innovator Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
206.	**Central Licensing Board in its 293rd meeting held on 20th November 2023 approved the grant of DML # 000987 (Formulation) for manufacturing facility of following dosage forms** **i. Oral Powder for Suspension (General)** **ii. Capsule (General)**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: 5A1-RZQ-135P Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 8952782388)
	The proposed proprietary name / brand name	LENZO 30MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Lansoprazole as enteric coated pellets…..... 30mg
	Pharmacotherapeutic Group of (API)	PPIs
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Vosta Capsule by Linta Pharma
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
207.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: 5Q9-S3Z-PJVN Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 8952782388)
	The proposed proprietary name / brand name	RECCO 100MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Racecadotril……..…100mg
	Pharmacotherapeutic Group of (API)	Antidiarrhoeals
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Hidrasec Capsule by Abbott
Evaluation by DD-PE&R:		
Decision: Approved with Innovator Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
208.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd**

		(DML # 000987) Chakri Interchange, Gangawala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: SA4-7LJ-SLH4 Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 5306428262)
	The proposed proprietary name / brand name	DEXXO 30MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole……..…30mg
	Pharmacotherapeutic Group of (API)	PPIs
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Razodex by Getz Pharma
Evaluation by DD-PE&R:		
Decision: Approved with Innovator Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
209.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: BMH-JZL-471T Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 12269432440)
	The proposed proprietary name / brand name	DEXXO 60MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole……..…60mg
	Pharmacotherapeutic Group of (API)	PPIs
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Razodex by Getz Pharma
Evaluation by DD-PE&R:		
Decision: Approved with Innovator Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

210.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: E99-D9Q-UJJA Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 27989330243)
	The proposed proprietary name / brand name	CARPI 1.5MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cariprazine Hydrochloride (USP) equivalent to Cariprazine …….…….....1.5mg
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotics
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Caripra by Genix Pharma

Evaluation by DD-PE&R:

Section	Observations	Status
3.2.P.2	Please submit source /manufacturer of reference product, batch #, Batch size, quantity procured.	Submitted
3.2.P.3	Please submit a brief chart of explanation of formulation to confirm QBD for assurance that risk assessment has been properly established for content uniformity.	Submitted

Decision: Approved with Innovator Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

211.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: E99-D9Q-UJJA Dated: 03-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 27989330243)
	The proposed proprietary name / brand name	CARPI 4.5MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cariprazine Hydrochloride (USP) equivalent to Cariprazine …….…….....4.5mg
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotics
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Caripra by Genix Pharma

Evaluation by DD-PE&R:

Section	Observations
3.2.P.2	Please submit source /manufacturer of reference product, batch #, Batch size, quantity procured.
3.2.P.3	Please submit a brief chart of explanation of formulation to confirm QBD for assurance that risk assessment has been properly established for content uniformity.

Decision: Approved with Innovator Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

212.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: ST9-S4Z-BUNQ Dated: 04-06-2024
	Details of fee submitted	PKR 75,000/-: 03-06-2024 (Slip # 40469173062)
	The proposed proprietary name / brand name	DABIGO 75MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dabigatran Etexilate Mesylate equivalent to Etexilate …….....75mg
	Pharmacotherapeutic Group of (API)	antithrombotic agents, direct thrombin inhibitors, ATC code: B01AE07.
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	PRADAXA® MHRA UK approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations
1.5.2	Please submit quantity of salt and base in the label claim as well as type of dosage form either pellets/granules/ powder etc.?
1.5.7	Please repeat the text of label as the local package insert of Pradaxa® currently carries warnings of this risk, including the recommendation to monitor for signs of bleeding or anemia.
3.2.S.3	Please submit additional specification for PSD for un-micronized drug substance and bulk density.
3.2.P.2	• Please submit source /manufacturer of reference product, batch #, Batch size, quantity procured. • Please clarify that why your product is in powder form while the innovator product is in pellets form? • Please submit evidence of procurement of reference product, its quantity & batch #. • Please explain that how comparative dissolution at pH 6.8 has been achieved in both reference and drug product while the innovator product claims that there is very low solubility at pH 6.8 due to low solubility profile of API?
3.2.P.3	As ingredients in your formulation are same as in reference product therefore you are required to explain process of palletization, equipment used.
3.2.P.5	• Please submit in process tests conducted for intermediate formulation to be filled in capsules. • Please submit details of physical appearance of pellets / powder / granules and its testing parameters. • Please submit reference for selection of dissolution media , speed and apparatus.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

213.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: BQ4-UU1-2T7S Dated: 04-06-2024
	Details of fee submitted	PKR 75,000/-: 03-06-2024 (Slip # 611549493)
	The proposed proprietary name / brand name	DABIGO 150MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dabigatran Etexilate Mesylate equivalent to Dabigatran …….....150mg
	Pharmacotherapeutic Group of (API)	antithrombotic agents, direct thrombin inhibitors, ATC code: B01AE07.
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	PRADAXA® MHRA UK approved formulation
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Section	Observations
1.5.2	Please submit quantity of salt and base in the label claim as well as type of dosage form either pellets/granules/ powder etc.?
1.5.7	Please repeat the text of label as the local package insert of Pradaxa® currently carries warnings of this risk, including the recommendation to monitor for signs of bleeding or anemia.
3.2.S.3	Please submit additional specification for PSD for un-micronized drug substance and bulk density.
3.2.P.2	• Please submit source /manufacturer of reference product, batch #, Batch size, quantity procured. • Please clarify that why your product is in powder form while the innovator product is in pellets form? • Please submit evidence of procurement of reference product, its quantity & batch #. • Please explain that how comparative dissolution at pH 6.8 has been achieved in both reference and drug product while the innovator product claims that there is very low solubility at pH 6.8 due to low solubility profile of API?
3.2.P.3	As ingredients in your formulation are same as in reference product therefore you are required to explain process of palletization, equipment used.
3.2.P.5	• Please submit in process tests conducted for intermediate formulation to be filled in capsules. • Please submit details of physical appearance of pellets / powder / granules and its testing parameters. • Please submit reference for selection of dissolution media , speed and apparatus.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

214.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Name, address of Manufacturing site.	**M/s Welcome Pakistan Trading Pharma (Pvt) Ltd (DML # 000987) Chakri Interchange, Gangawala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: QN4-VJV-G8BR Dated: 05-06-2024
	Details of fee submitted	PKR 30,000/-: 29-05-2024 (Slip # 0715202270)
	The proposed proprietary name / brand name	OZEPRA 40MG CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Omeprazole as enteric coated pellets…..... 40mg
	Pharmacotherapeutic Group of (API)	PPIs
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Risek by Getz
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
215.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Skywin Pharmaceutical (DML # 000971) Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road Lahore.**
	Name, address of Manufacturing site.	**M/s Skywin Pharmaceutical (DML # 000971) Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: ML9-64U-T2NV Dated: 05-06-2024
	Details of fee submitted	PKR 30,000/-: 13-12-02023 (Slip #5264566559)
	The proposed proprietary name / brand name	MEDROX injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml Contains: Medroxyprogesterone acetate ……. 150 mg
	Pharmacotherapeutic Group of (API)	A Derivative of Progesterone.
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	MEDROXY DEPO 150 mg/ml Injection. Global Pharma
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Item No. 02: Routine Cases

216.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284) 29-30 Sector 27 Korangi Industrial Area Karachi.**

	Name, address of Manufacturing site.	**M/s Getz Pharma (Pvt) Ltd. (DML # 000284)** **29-30 Sector 27 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29755 Dated: 20-10-2022
	Details of fee submitted	PKR 75,000/-: 06-10-2022 (Slip # 902475846544)
	The proposed proprietary name / brand name	Flutika DPI capsule 200 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-dispensed dose contains: Fluticasone Furoate …….… 200 mcg
	Pharmaco-therapeutic Group of (API)	Drugs for obstructive airways diseases, corticosteroids
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA approved Breo Ellipta
	For generic drugs (me-too status)	Relvar Ellipta by GSK
Evaluation by DD-PE&R:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
217.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Health Care (Pvt.) Ltd (DML # 000782)** **Plot No. 33 Punjab Industrial Estate Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29746 Dated: 20-10-2022
	Details of fee submitted	PKR 30,000/-: 18-10-2022
	The proposed proprietary name / brand name	Tablet Pytol Duo 200/500
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen …… 200 mg Paracetamol …… 500 mg
	Pharmaco-therapeutic Group of (API)	Musculoskeletal system, anti-inflammatory and antirheumatic products, non-steroids, propionic acid derivatives. Ibuprofen combinations ATC Code: M01AE51.
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA approved Formulation.
	For generic drugs (me-too status)	Provas Duo 500/200 by Sami Pharmaceuticals

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of that country and should be valid till date.	Submitted

3.2.P.8	Please submit the relevant data of stability batches (chromatograms, calculation sheets, raw data etc).	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 03: <u>Export Facilitation Cases:</u>

218.	**Name, address of Applicant / Marketing Authorization Holder**	**Genome Pharmaceuticals (Pvt.) Ltd (DML # 000454) Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK).**
	Name, address of Manufacturing site.	**Genome Pharmaceuticals (Pvt.) Ltd (DML # 000454) Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK).**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: BRA-5GJ-JQDG Dated: 05-06-2024
	Details of fee submitted	PKR 75,000/-: 28-02-2024 (Slip # 570751617)
	The proposed proprietary name / brand name	Finro 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 10 mg
	Pharmaco-therapeutic Group of (API)	a nonsteroidal mineralocorticoid receptor antagonist (Diuretics)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved KERENDIA®
	For generic drugs (me-too status)	N/A

Evaluation by DD-PE&R:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

219.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503) A-115 S.I.T.E Super Highway Karachi.**
	Name, address of Manufacturing site.	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503) A-115 S.I.T.E Super Highway Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: 3PP-5Y8-VQXQ Dated: 06-06-2024
	Details of fee submitted	PKR 30,000/-: 19-04-2024 (Slip # 0470683993)
	The proposed proprietary name / brand name	Sodium Chloride 0.9% 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Sodium Chloride …… 9 mg
	Pharmaco-therapeutic Group of (API)	Parenteral Electrolyte, Osmotherapy Agent, Sodium Supplement
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Locally registered

EVALUATION OF DATA	
GMP status of the firm	GMP Validity: 14-02-2025
Evidence of approval of manufacturing facility	Central Licensing Board in its 291st meeting granted renewal of DML # 000503 including Liquid Sterile (ampoule & vial) General.
Proposed Pack size	5 ml type I glass ampoules
Proposed unit price	As per SRO
Name and address of API manufacturer.	Name: K+S Minerals and Agriculture Address: Bertha-von-Suttner-Ste.7, 34131 Kassel Karlstr. 80, 47495 Rheinberg Germany.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 06 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** NaCl 0.9% solution **Manufacturer:** Getz Pharma **Testing Parameters:** USP Specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	615300
Description of Pack (Container closure system)	5ml clear glass ampoule Type-I
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6,12 & 24 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	6.5 L	6.5 L	6.5 L
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	08-2023	08-2023	08-2023
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 15-09-2025
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 250 grams **Dated:** 31-05-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

220.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503)** **A-115 S.I.T.E Super Highway Karachi.**
	Name, address of Manufacturing site.	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503)** **A-115 S.I.T.E Super Highway Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: V6T-EH5-6Z4H Dated: 06-06-2024
	Details of fee submitted	PKR 30,000/-: 19-04-2024 (Slip # 3514605343)
	The proposed proprietary name / brand name	Lydocaine 1% Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Lidocaine Hydrochloride.....10mg

	Pharmaco-therapeutic Group of (API)	Diluent
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Locally registered

EVALUATION OF DATA	
GMP status of the firm	GMP Validity: 14-02-2025
Evidence of approval of manufacturing facility	Central Licensing Board in its 291st meeting granted renewal of DML # 000503 including Liquid Sterile (ampoule & vial) General.
Proposed Pack size	2 ml type I glass ampoules
Proposed unit price	As per SRO
Name and address of API manufacturer.	Name: APEX HEALTHCARE LIMITED Address: 4710, 4711-GIDC ESTATE, ANKLESHWAR -393 002, GUJARAT, INDIA.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 06 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** NaCl 0.9% solution **Manufacturer:** Getz Pharma **Testing Parameters:** USP Specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	LHCP1080820		
Description of Pack (Container closure system)	2ml clear glass ampoule Type-I		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,12 & 24 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	05-2021	05-2021	05-2021
No. of Batches	02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 15-09-2025
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 500 grams **Dated:** 27-08-2020
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by DD-PE&R:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

221.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503)** **A-115 S.I.T.E Super Highway Karachi.**
	Name, address of Manufacturing site.	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503)** **A-115 S.I.T.E Super Highway Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Track ID: GEV-66W-1QHQ Dated: 06-06-2024
	Details of fee submitted	PKR 30,000/-: 22-04-2024 (Slip # 7261226432)
	The proposed proprietary name / brand name	Water for Injection 5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: WFI …… 5ml
	Pharmaco-therapeutic Group of (API)	Diluent
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved
	For generic drugs (me-too status)	Locally registered

EVALUATION OF DATA	
GMP status of the firm	GMP Validity: 14-02-2025

Evidence of approval of manufacturing facility	Central Licensing Board in its 291st meeting granted renewal of DML # 000503 including Liquid Sterile (ampoule & vial) General.
Proposed Pack size	5 ml type I glass ampoules
Proposed unit price	As per SRO
Name and address of API manufacturer.	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	N/A
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** WFI **Manufacturer:** Barrett **Testing Parameters:** USP Specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	N/A		
Description of Pack (Container closure system)	5ml clear glass ampoule Type-I		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,12 & 24 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	10-2023	10-2023	10-2023
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 15-09-2025
Documents for the procurement of API with approval from DRAP (in case of import).	**N/A**
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system

Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by DD-PE&R:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Item No. 04: Deferred cases of Form 5F

222.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd.** **(DML # 000958)** **Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23479 dated 22-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 10-08-2023 Slip # 1666778434
	The proposed proprietary name / brand name	Stomy 40 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet: Famotidine …… 40mg
	Pharmacotherapeutic Group of (API)	H_2 Receptor Antagonist
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10s, 20s, 30s & 100s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Famot 40 mg Tablet

		Manufacturer: M/s Shaigan Pharmaceuticals
	Name and address of API manufacturer.	**Name:** M/s Vaasavaa Pharmaceuticals (Pvt.) Ltd **Address:** Plot No. C-216 & 217, MIDC ,Chincholi, Solapur-413 255, Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 48 months**. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Ulcenil 40 mg **Manufactured by:** Siza Pharma **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Vaasavaa Pharmaceuticals (Pvt.) Ltd **Address:** Plot No. C-216 & 217, MIDC,Chincholi, Solapur-413 255, Maharashtra, INDIA.
API Lot No.	20225804
Description of Pack (Container closure system)	Parrot green, round biconvex tablet embossed with PHARMAN on one side and other side is plane.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	FM22-001	FM22-002	FM22-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	12-05-2023	12-05-2023	12-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit the GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.1	• In Section 1.5.2 of Module I, the label claim describes drug product as **film coated tablet** while in the formulation / pharmaceutical development of drug product, ingredients for film coating are not present. You are therefore required to submit evidence approval of uncoated tablet of famotidine in reference regulatory authority and also in Pakistan. • You are required to submit batch manufacturing record of three stability batches along with Master formula record.	Film coated tablet
3.2.P.8	• Please submit DRAP clearance documents for procurement of API.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 05: <u>Form 5 deferred Cases:</u>

223.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.188 No. dated 19/12/2008

<table>
<tr><td></td><td></td><td>Differential fee (Photocopy) of Rs.12,000/- submitted on 26/10/2017</td></tr>
<tr><td></td><td>Composition</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg
Vitamin B6….10mg</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Vitamin and mineral formulations</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td></td><td>Pack Size & Demanded Price</td><td>As per S.R. O</td></tr>
<tr><td></td><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td></td><td>Me-too Status</td><td>CaC-1000 sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro</td></tr>
<tr><td></td><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.</td></tr>
<tr><td></td><td>Previous Decision of 295th meeting</td><td>Registration Board in its 295th meeting decided as under:
Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td></td><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table>
It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent.</td></tr>
<tr><td colspan="3"><u>Decision of 296th meeting:</u>
Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.</td></tr>
<tr><td colspan="3">Remarks of the Evaluator: Densical sachet of Platinum pharma Karachi was registered with Reg No. 042153 dated 23-01-2006 and having following composition:
Each Sachet contains:
Calcium Lactate ….1000mg
Calcium Carbonate….327mg</td></tr>
</table>

	Vitamin C ….500mg Vitamin D….4mg Vitamin B6….10mg The applied formulation has Calcium Lactate Gluconate 1000mg while me too registered has Calcium Lactate 1000mg.
	Decision: Registration Board in line with vitamin-mineral policy discussed by Registration Board in its 291st and 295th meeting decided to Approve with innovator's specification with following composition: **Each Sachet contains:** **Calcium Lactate ….1000mg** **Calcium Carbonate….327mg** **Vitamin C ….500mg** **Vitamin D….4mg** **Vitamin B6….10mg** **Firm shall submit fee of Rs:30000/- for revision of formulation before issuance of registration letter.**

Export Facilitation Desk

Item No. I: REGISTRATION OF DRUGS EXCLUSIVELY FOR EXPORT PURPOSE

Sr. No.	Name of Manufacturer & Fee Details	Brand Name & Composition	Generic/RRA Status	Application ID
1.	**High-Q Pharmaceuticals,** 44-45 B Korangi Creek Road, Karachi License Number: **000597** Fee Paid: 75000.0 Challan No: 8309414170	**Polymalt Syrup** Each 5ml contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron……..125mg	**Not Available** Purchase Order from Ivory Coast	**7YB-9N5-AY2W**

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Post Registration-I Section

Case No. 01: Change of Registration Holder (MA Holder) along with Change in manufacturing site of Zoloft® Tablet.

29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Change of Manufacturing Site & Change of Registration Holder (MA Holder)	
	From **M/s Pfizer Pakistan Ltd. (DML # 000025)** **B-2-SITE Karachi.**	**To** **M/s M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1810 Dated: 26-01-2024

	Details of fee submitted	PKR 30,000/-: 19-01-2024 (Slip # 35690366355)
	The proposed proprietary name / brand name	**Tablet Zoloft 50 mg** ***(Reg. # 020855)*** **Initial Registration:** Year 1997 **Transfer of Registration:** 25-03-2010 Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Sertraline (as HCl) …… 50 mg
	Pharmacotherapeutic Group of (API)	Anti-psychotics
	Reference to Finished product specifications	USP Specification

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 12-06-2023.
Evidence of approval of manufacturing facility	Central Licensing Board in its 275th meeting held on 20th June 2020 approved the renewal of DML # 000348 Including Tablet (General) Section.
Proposed Pack size	ALU-PVC Blisters
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zoloft® USFDA approved formulation
For generic drugs (me-too status)	Zoloft® by Pfizer
Name and address of API manufacturer.	Wanbury Limited India Division of Doctor Organicc Chemicals Address: K. Illindalaparru, Irragavaram Mandal, West Godavari District Tanuku Andhra Pradesh India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zoloft 50 mg Tablet **Manufacturer:** Pfizer Pakistan **Testing parameters:** USP specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	SHO2360723		
Description of Pack (Container closure system)	ALU-PVC Bister further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	132DS01	132DS02	132DS03

Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	09-2023	09-2023	09-2023
Date of Initiation	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 08-12-2024
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 6.5 kg **Dated:** 10-08-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

- AGP has submitted NOC issued by Pfizer Pakistan Limited mentioning the products including Zoloft.
- The asset purchase agreement describe the mode of technology transfer is documentation based and includes know how of the manufacturing procedures. The monograph of drug product as well as API are now available in official Pharmacopeia thus the impurity profile of API is now public.
- The API manufacturer has been changed from **Pfizer Asia Manufacturing PTE Singapore** to **Wanbury Limited, India.**
- As per MaV-03 guidelines, firm has submitted comparison of batch analysis report as comparative dissolution profile of previously manufactured batches with the drug product manufactured at AGP.
- There is no change in the formulation of the drug product.
- The primary container material is also same i.e. (ALU/PVC Blister)

Decision: Registration Board acceded to the request of the firm for Change of Registration Holder (MA Holder) along with manufacturing site as under

Tablet Zoloft 50 mg *(Reg. # 020855)*

Existing MAH & Manufacturing site	**Proposed MAH & Manufacturing site**
M/s Pfizer Pakistan Ltd. (DML # 000025) B-2-SITE Karachi.	M/s M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Change of Manufacturing Site & Change of Registration Holder (MA Holder)	
	From M/s Pfizer Pakistan Ltd. (DML # 000025) B-2-SITE Karachi.	**To M/s M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1373 Dated: 22-01-2024
	Details of fee submitted	PKR 30,000/-: 19-01-2024 (Slip # 19153984475)
	The proposed proprietary name / brand name	**Tablet Zoloft 100 mg** ***(Reg. # 020855)*** **Initial Registration:** Year 1997 **Transfer of Registration:** 25-03-2010 Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Sertraline (as HCl) ……. 100 mg
	Pharmacotherapeutic Group of (API)	Anti-psychotics
	Reference to Finished product specifications	USP Specification

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 12-06-2023.
Evidence of approval of manufacturing facility	Central Licensing Board in its 275th meeting held on 20th June 2020 approved the renewal of DML # 000348 Including Tablet (General) Section.
Proposed Pack size	ALU-PVC Blisters
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zoloft® USFDA approved formulation
For generic drugs (me-too status)	Zoloft® by Pfizer
Name and address of API manufacturer.	Wanbury Limited India Division of Doctor Organicc Chemicals Address: K. Illindalaparru, Irragavaram Mandal, West Godavari District Tanuku Andhra Pradesh India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zoloft 100 mg Tablet **Manufacturer:** Pfizer Pakistan **Testing parameters:** USP specification
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	SHO2360723
Description of Pack (Container closure system)	ALU-PVC Bister further packed in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	133DS01	133DS02	133DS03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	09-2023	09-2023	09-2023
Date of Initiation	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Validity: 08-12-2024
Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 6.5 kg **Dated:** 10-08-2023
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by DD-PE&R:

- AGP has submitted NOC issued by Pfizer Pakistan Limited mentioning the products including Zoloft.
- The asset purchase agreement describe the mode of technology transfer is documentation based and includes know how of the manufacturing procedures. The monograph of drug product as well as API are now available in official Pharmacopeia thus the impurity profile of API is now public.
- The API manufacturer has been changed from **Pfizer Asia Manufacturing PTE Singapore** to **Wanbury Limited, India.**
- As per MaV-03 guidelines, firm has submitted comparison of batch analysis report of previously manufactured batches with the drug product manufactured at AGP.
- There is no change in the formulation of the drug product.
- The primary container material is also same i.e. (ALU/PVC Blister)

Decision: Registration Board acceded to the request of the firm for Change of Registration Holder (MA Holder) along with manufacturing site as under

Tablet Zoloft 100 mg *(Reg. # 020855)*

Existing MAH & Manufacturing site	**Proposed MAH & Manufacturing site**
M/s Pfizer Pakistan Ltd. (DML # 000025) B-2-SITE Karachi.	M/s M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.

Case No. 02: <u>Change of Registration Holder (MA Holder)</u> <u>along with Change in Manufacturing Site</u>

31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.**
	Change of Registration Holder (MA Holder)	
	From M/s Martin Dow Ltd. Plot No. 37 Sector 19 Korangi Industrial Area Karachi.	**To M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.**
	Change in manufacturing site	

	From **M/s Cenexi Sas Fontenary, Souis Bois, France.**	To **M/s Martin Dow Marker Ltd. (DML # 000028)** **7-Jail Road Quetta.**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Track ID. PVR-L8Y-V9UW dated 05-06-2024
	Details of fee submitted	PKR 30,000/-: dated: 05-04-2024 (Invoice # 48378832)
	The proposed proprietary name / brand name	Valium Injection 10mg/2ml ***(Reg. # 000584)***
		Initial Registration: August 1976
		Transfer of Registration: 10-03-1988
		Transfer of Registration: 17-12-1997 **Transfer of Registration:** 26-06-2001 **Transfer of Registration:** 29-06-2010 **Transfer of Registration:** 09-03-2016
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Diazepam ……...…..…….…… 10 mg
	Pharmaceutical form of applied drug	Sterile liquid for injection
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	A Product of Schazoo
	GMP status of the Finished product manufacturer	cGMP Certificate valid till 14-01-2026
	Name and address of API manufacturer.	M/s FIS Fabbrica Italiana Sintetici S.P.A Viale Milano, 26- 36075 Montecchio Maggiore (VI) Italy.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Valium® **Manufacturer:** Cenexi France **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s FIS Fabbrica Italiana Sintetici S.P.A Viale Milano, 26- 36075 Montecchio Maggiore (VI) Italy.		
API Lot No.	202304180044		
Description of Pack (Container closure system)	Type I transparent glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**PDS-101/23**	**PDS-102/23**	**PDS-103/23**
Batch Size	2500 Ampoules	2500 Ampoules	2500 Ampoules
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	08-2023	08-2023	08-2023
No. of Batches	03		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
15.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dated:** 17-08-2023 **Quantity:** 86.6 grams
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.

17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- The case has been evaluated as per DRAP guidelines for PRV cases – MaV-3 (Change in manufacturing site).
- NOC has been received from previous manufacturer along with documentation of knowhow for technology transfer of drug product.
- NOC from M/o Narcotics has been received regarding issuance quota allocation for controlled substance (import/export) for Martin Dow Quetta.
- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- Firm has submitted Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).
- There is no change in source of API.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder)along with change of manufacturing site as under

Valium Injection 10mg/2ml *(Reg. # 000584)*

Existing MAH	**Proposed MAH & Manufacturing site**
M/s Martin Dow Ltd. (DSL Holder) Plot No. 37 Sector 19 Korangi Industrial Area Karachi.	M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.
Import from	
M/s Cenexi Sas Fontenary, Souis Bois, France.	

32.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.**
	Change of Registration Holder (MA Holder)	
	From M/s Martin Dow Ltd Plot No. 37 Sector 19 Korangi Industrial Area Karachi.	**To M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.**
	Change in manufacturing site	
	From M/s Cenexi Sas Fontenary, Souis Bois, France.	**To M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Track ID. 5ZY-X8M-M4LZ dated 05-06-2024
	Details of fee submitted	PKR 30,000/-: dated: 05-04-2024 (Invoice # 69928130610)
	The proposed proprietary name / brand name	Dormicum Ampoule 5mg/5ml ***(Reg. # 014929)***
		Initial Registration: 24-02-1994

		Transfer of Registration: 06-06-2005
		Transfer of Registration: 29-06-2010
		Renewal Status: Valid
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Midazolam……..5mg
	Pharmaceutical form of applied drug	Sterile liquid for injection
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Swissmedic Switzerland
	For generic drugs (me-too status)	IDZO by Sami Pharma
	GMP status of the Finished product manufacturer	cGMP Certificate valid till 14-01-2026
	Name and address of API manufacturer.	M/s FIS Fabbrica Italiana Sintetici S.P.A Viale Milano, 26- 36075 Montecchio Maggiore (VI) Italy.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Comparator / Innovator Product:** Dormicum® **Manufacturer:** Cenexi France **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s FIS Fabbrica Italiana Sintetici S.P.A Viale Milano, 26- 36075 Montecchio Maggiore (VI) Italy.		
API Lot No.	202306210017		
Description of Pack (Container closure system)	Type I transparent glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, (Months)		
Batch No.	**PDS-164/23**	**PDS-165/23**	**PDS-166/23**
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	11-2023	11-2023	11-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dated:** 17-10-2023 **Quantity:** 100 mg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

- The case has been evaluated as per DRAP guidelines for PRV cases – MaV-3 (Change in manufacturing site).
- NOC has been received from previous manufacturer along with documentation of knowhow for technology transfer of drug product.
- NOC from M/O Narcotics has been received regarding issuance quota allocation for controlled substance (import/export) for Martin Dow Quetta.
- Firm has submitted Pharmaceutical Equivalence of their drug product for pervious and proposed manufacturing site and found satisfactory.
- Firm has submitted Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the approved site
- The formulation of the drug product is same for both manufacturing sites (Previous & existing).
- There is no change in source of API.

Decision: Registration Board acceded to the request of the applicant for Change of Registration Holder (MA Holder) along with change of manufacturing site as under

Dormicum Ampoule 5mg/5ml *(Reg. # 014929)*

Existing MAH **Proposed MAH & Manufacturing site**

M/s Martin Dow Ltd. (DSL Holder) Plot No. 37 Sector 19 Korangi Industrial Area Karachi.	M/s Martin Dow Marker Ltd. (DML # 000028) 7-Jail Road Quetta.
Import from M/s Cenexi Sas Fontenary, Souis Bois, France.	

Item No. V. Division of Quality Assurance & Lab Testing

S NO.	CASE TITLE
1	MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD GENTAMED INJECTION REG. NO. 053243, BATCH NO. A-20434 MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.
2	MANUFACTURE & SALE OF SUB-STANDARD FLAGYNASE SUSPENSION, REG. NO. 087528, BATCH NO. 0224 MANUFACTURED BY M/S. ARIES PHARMACEUTICALS (PVT) LTD., PESHAWAR
3	MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. 440 MANUFACTURED BY M/S. KARACHI PHARMACEUTICAL LABORATORIES, KARACHI (F. No. 03-51/2022-QC)
4	MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.
5	MANUFACTURE & SALE OF SUB-STANDARD LEFIN PEDIATRIC SUSPENSION, REG. NO. 000404, BATCH NO. 332V, MANUFACTURED BY M/S. LEAMA CHEMI PHARMA (PVT) LTD. PESHAWAR.
6.	SUBSTANDARD ESPEZAR CAPSULE MFG. BY AVANT PHARMACEUTICALS (PVT.) LTD., HUB, BALOCHISTAN.

CASE NO 01: <u>MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD GENTAMED INJECTION REG. NO. 053243, BATCH NO. A-20434 MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.</u>

The Federal Inspector of Drug, DRAP, Karachi inspected the premises of M/s; Muzammil Brother, Shop #15, Maji Market, No. 4, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road Karachi wherein following sample of drug was taken for the purpose of test/analysis on prescribed Form-3. Details are:

S.No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	CDL Remarks
01	Gentamed Injection 2ml Ampoules (Gentamicin)	053243	A-20434	12/2020	12/2022	M/s. Mediate Pharmaceutical (Pvt) Ltd. 150-151, Sector-24, Korangi Industrial Area, Karachi.	Adulterated & Sub-Standard on the basis of description.

02. Results of CDL on the basis of which sample under reference has been declared as Adulterated & Substandard quality are reproduced as under: -

<u>i. Reports No. KQ.120/2021(Initial):</u>

S.No.	Test	Acceptance Criteria	Result	Reference

1.	Description	Colourless Solution.	**Colourless solution in colourless glass ampoule, containing black colour particles visible to the naked eye. Does not Comply.**	Mfg. Specs.
2.	Identification.	The identification test must identify Gentamycin Sulphate.	Complies.	BP 2020
3	pH	3.0 to 5.5	3.51- Complies	BP 2020

Note: Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.

Remarks:- 1) The sample is of **"Adulterated and Sub-Standard"** quality under the Drugs Act, 1976.

ii. Reports No. KQ.120/2021 (Final):

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Colourless Solution.	**Colourless solution in colourless glass ampoule, containing black colour particles visible to the naked eye. Does not Comply.**	Mfg. Specs.
2.	Identification.	The identification test must identify Gentamycin Sulphate.	Complies.	BP 2020
3	pH	3.0 to 5.5	3.51- Complies	BP 2020
4	Bacterial Sterility	Must be sterile.	Complies.	BP 2020
5	Bacterial Endotoxin	7.11U/ml.	Complies.	BP 2020
6	**Assay.** Gentamicin. (Label Claim 80mg/2ml)	95.0% to 105%	95.6%- Complies	BP 2020

Remarks:- 1) The sample is of **"Adulterated and Sub-Standard"** quality under the Drugs Act, 1976.

03. Recall to manufacturer had been issued dated 26-10-2023.

04. FID Karachi asked Ms. Muzammil Brother, Karachi to provide bill warranty in connection with the purchase of above said drug along with subsequent reminders. Letter was returned undelivered with the remarks that shop was closed and they left the premises.

05. FID Karachi issued an explanation letter to M/s. Mediate Pharmaceutical (Pvt) Ltd. Korangi Industrial Area, Karachi for explaining their position in the matter of manufacturing/selling of above mentioned Adulterated and Sub-Standard drug.

06. M/s. Mediate Pharmaceutical (Pvt) Ltd. 150-151, Sector-24, Korangi Industrial Area, Karachi provided bill warranty in connection with the sale of above said drug of M/s; Ahmed Enterprises, Karachi.

07. FID asked to M/s. Ahmed Enterprises, Karachi explain their position. They submitted the stock detail report / Sale record.

08. FID recommended that:

I. M/s. Mediate Pharmaceutical (Pvt) Ltd. 150-151, Sector-24, Korangi Industrial Area, Karachi found involved in manufacturing & selling substandard & adulterated drug Gentamed Injection 2ml Ampoules Batch No. A20434 and violated the section 23(1)(a)(iv), 23(1)(a)(v) of the Drugs Act 1976 and rules framed thereunder. Therefore, action may be initiated under section 42 of the Drugs Act 1976.

II. M/s; Muzammil Brother, Shop #15, Maji Market, No. 4, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road Karachi found involved in selling of sub-Standard & adulterated drug and violated the section 23(1)(a)(iv), 23(1)(a)(v) & 23(1)(i) of the Drugs Act 1976 of the Drugs Act 1976, punishable under section 27 of the Drugs Act 1976.Therefore licensing authority may be requested to cancel his Drug Sale License No. 2461.

09. A show cause notice was issued from QA&LT Division to Ms. Mediate Pharmaceutical (Pvt) Ltd., Karachi vide letter F.No.03-22/2021-QC dated 24th January 2024.

10. Ms. Mediate Pharmaceutical (Pvt) Ltd., Karachi has submitted the reply that they checked their batch optically, no any ampoule found with black particles. Further, they mentioned that they were stopped the production of Gentamycin Injection in ampoule, last batch was manufactured in Jan-2021. They were destructed all recall stock of Gentamycin ampoules; destruction certificate is attached. They added that they will no longer manufacture the said drug in ampoule because it seems that it is not stable in ampoule, further they are going to apply for de register this product as we are not manufacturing this in a few years.

11. Firm has been called for personal hearing.

12. Proceedings and Decision of 336th Meeting of Registration Board.

M/s. Mediate Pharmaceutical (Pvt) Ltd., Karachi vide letter No. Nil dated 04-06-2024 submitted that their Managing Director is out of country due to performance of Hajj and unable to appear on personal hearing and requested to provide another chance of personal hearing.

Registration Board considered the request of the firm and decided to provide another chance of personal hearing to the firm.

CASE NO. 02: MANUFACTURE & SALE OF SUB-STANDARD FLAGYNASE SUSPENSION, REG. NO. 087528, BATCH NO. 0224 MANUFACTURED BY M/S. ARIES PHARMACEUTICALS (PVT) LTD., PESHAWAR.

The Federal Inspector of Drug, DRAP, Karachi inspected M/s National Institute of Child Health, (NICH), Rafeeqi Shaheed Road Karachi on 03-02-2022 wherein following sample along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

02. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Remarks
Flagynase Suspension BP (Metronidazole)	M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar.	087528	0244	11-21	11-23	Sub-Standard on pH

03. Results of CDL on the basis of which sample under reference has been declared as Adulterated & Substandard are reproduced as under: -

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Metronidazole Benzoate.	Complies.	BP 2020
2.	pH	**5.0 to 6.5**	**4.63 Does not comply.**	BP 2020
3.	**Assay** Metronidazole (Label Claim 200mg/5ml)	95.0% to 105.0%	97.17% Complies**.** 107.9% Complies.	BP 2020

Remarks: 1) *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

04. FID DRAP Karachi submitted the case along with firm's reply that:

"[...] they have test the retained sample of Flagynase 60ml suspension and have found it as per specification.

M/s. Aries pharma* did not challenge *the test report. FID submitted that portion of sample lying with the Board* may be got retested *from Appellate Laboratory NIH Islamabad under section 22(5) of Drugs Act 1976 [...]"

05. In view of FID's request, letter was sent to get a response from FID for the reason(s) to submit the case for retesting.

06. FID-III, Karachi responded vide letter No. F. DHB-12 to 017/2022-FID-II(K) dated 26th Oct, 2023, stating the then FID did not request for retesting and it was inadvertently typed hence it may be considered as typo error, as informed by her. The case is now submitted for the consideration of Board.

07. Proceedings and Decision of 331st Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar and CDL, DRAP Karachi was presented before Registration Board.

The Board deliberated the case in detail and decided not to accede the firm's request of appellate testing and to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar and called them for personal hearing before Registration Board.

08. Show cause notice to the firm was issued vide office letter No. F.No.03-38/2023-QC (331-RB) dated 13th December 2023.

09. Firm has been called for personal hearing.

10. Proceedings and Decision of 336th Meeting of Registration Board.

Mr. Noor Faraz, Production Manager, Mr. Shiraz Khan, QC Manager and Mr. Abdul Haseeb, Regulatory Officer appeared before the Board. They said that stability study of the product is ongoing and request for inspection by the panel.

"The Board after considering the facts of the case and after thorough deliberations decided:

i. Suspension of the Registration of Flagynase Suspension, Registration No. 087528 manufactured by M/s. Aries Pharmaceuticals (Pvt) Ltd., Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.

ii. Submission of RCA and CAPA by the firm.

iii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.

iv. Firm shall submit complete recall status of aforementioned batch as per Recall Guidelines Doc no. QALT/GL/RA/001 to the QALT Division, DRAP, Islamabad.

CASE NO. 03: MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. 440 MANUFACTURED BY M/S. KARACHI PHARMACEUTICAL LABORATORIES, KARACHI.

The Federal Inspector of Drug, DRAP, Karachi inspected M/s Sindh Government Children Hospital, North Nazimabad, Karachi on 16-09-2022 wherein following sample along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Remarks
Water for injection	M/s. Karachi Pharmaceutical Laboratories, Karachi	012570	440	Jun 22	Jun 25	Sub-Standard on conductivity.

02. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide their test report No.KQ.9-22-000164 dated 11-10-2022 and No.KQ.9-22-000164 (Final) dated 28-10-2022. Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under: -

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Acidity or Alkalinity	Meet the requirements.	Complies.	BP 2020
2.	Conductivity	Not more than 25uS/cm	**48.09uS/cm- Does not comply.**	BP 2020
3	Sterility	Must be sterile	Complies	BP 2020
4	Bacterial endotoxin	Not more than 0.25IU/ml	**Does not comply**	BP 2020
5	Visible particulate matter	Meets the requirement	Complies	BP 2020

Remarks: The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

04. FID, DRAP, Karachi informed that the firm has requested for retesting.

05. As per decision of 313th meeting of Registration Board regarding appellate testing, Firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 21-06-2023

06. Ms. Karachi Pharmaceutical Laboratories Karachi submitted their reply vide Ref. KPL/HR/7/23 dated 03-07-2023 along with OOS investigation, OOS results reproduced as:

"Handling of Out of specifications OOS results for samples in Karachi Pharmaceutical Laboratories. It is the policy of Karachi Pharmaceutical Laboratories that written procedures shall be followed to carry out laboratory investigations/product retest and assign probable cause and initiate appropriate CAPA for OOS results of samples."

07. Firm submitted recall log, the percentage of recall is **89.24%.** Area FID has been requested for verification of recalled stock, reply awaited.

08. Technical Evaluation of OOS Investigation:

i. The product was declared as sub-standard on the basis of conductivity and bacterial endotoxin.
ii. There may be issues during manufacturing processes, quality of API, and instability of product.
iii. Firm submitted reply without scientific justifications and clear conclusion, further, flow chart for investigation of OOS was not attached as mentioned in the conclusion. While CDL Karachi submitted that the final decision of the report is OOS valid.

09. Proceedings and Decision of 331st Meeting of Registration Board.

i. Out of Specification (OOS) investigations and testing records submitted by Ms. Karachi Pharmaceutical Laboratories Karachi and CDL, DRAP Karachi was presented before Registration Board.
ii. The Board deliberated the case in detail and decided not to accede the firm's request of appellate testing and to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to Ms. Karachi Pharmaceutical Laboratories Karachi and called them for personal hearing before Registration Board.

10. Show cause notice to the firm was issued vide office letter No. F.No.03-38/2023-QC (331-RB) dated 13th December 2023

11. Firm has been called for personal hearing as per decision of the Registration Board.

12. Proceedings and Decision of 336th Meeting of Registration Board.

No person on behalf of M/s. Karachi Pharmaceutical Laboratories Karachi appeared before the Board. Registration Board decided to provide last chance of personal hearing to the firm.

Case No. 04: MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.

The Federal Inspector of Drug, DRAP, Karachi visited the premises of M/s Mediate Pharmaceutical (Pvt.) Ltd., Karachi on 14-04-2021 wherein following samples along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL remarks
Hitaxime 1gm Injection (vial) Cefotaxime	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044109	V-20059	11-2020	11-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20017	07-2020	07-2023	Substandard on the basis of Bacterial endotoxin.
Hilixophin 500mg Injection (vial) Ceftriaxone	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044105	V-20085	12-2020	12-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20024	12-2020	12-2023	Substandard on the basis of Bacterial endotoxin.

02. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

i. Reports No. KQ.91/2021:

(STERILE WATER FOR INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	**Bacterial Endotoxin**	**Less than 0.25 EU per ml.**	**Does not comply.**	**USP 43**

(HITAXIME 1GM INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Offwhite powder in clear glass vial	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Cefotaxime Sodium.	Complies.	USP 43
3.	pH	4.5 to 6.5	Complies.	USP 43
4.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
5.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Cefotaxime (label claim 1gm/vial)	90.0% to 115.0%	105.0% complies	USP 43

NOTE: Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

ii. Reports No. KQ.92/2021:

(STERILE WATER FOR INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Less than 0.25 EU per ml.	**Does not comply.**	USP 43

(HILIXOPHIN 500MG INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Off white powder in clear glass vial.	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Ceftriaxone Sodium.	Complies.	USP 43
3.	pH	6.0 to 8.0	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Ceftriaxone.	90.0% to 115.0%	100.3% complies	USP 43

	(label claim 500mg/vial)			

NOTE: **Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.**

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

03. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated that:

"[…] we are requesting you to retest Bacterial Endotoxin test of both WFI injections, for this purpose we retest samples in our QC Dept. with three different kits and find results as given below:

Test performed	***Bioendo***	***Lonza***	***Cape-Cod***
Bulk sample	*Fail*	*Pass*	*Pass*
Sample after autoclave	*Fail*	*Pass*	*Pass*
W-20017	*Fail*	*Pass*	*Pass*
GSK WFI SPW9/1 (02-2018)	*Fail*	*Pass*	*Pass*

04. As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 26-01-2022.

05. M/s. Mediate Pharmaceutical Pvt Ltd., Karachi replied they conducted investigation but found no fail results. Firm has mentioned that they cross checked the recalled product and QC retention samples and performed bacterial endotoxin test by using three different kits out of which results of Bioendo endotoxin kit were not satisfactory. Details are:

S.no	**Reagent used**	**Results**
Lonza Endotoxin Kit		
1	Lysate reagent	Satisfactory
2	Control standard endotoxin	Satisfactory
3	Lal reagent water	Satisfactory
Cape code Endotoxin Kit		
4	Lysate reagent	Satisfactory
5	Control standard endotoxin	Satisfactory
6	Lal reagent water	Satisfactory
Bioendo Endotoxin Kit		
7	Lysate reagent	Un-satisfactory
8	Control standard endotoxin	Un-satisfactory
9	Lal reagent water	Un-satisfactory

06. While CDL, Karachi submitted OOS investigation, the result was OOS is confirmed.

Technical Evaluation of the case:

- The product was declared sub-standard on the basis of results of Bacterial endotoxin.
- Endotoxin test performed by Gel Clot method both by firm and CDL as given in USP 43.
- The method is based on visual inspection of the sample after incubation for presence of gel or otherwise.

07. Proceedings and Decision of 326th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and CDL, DRAP Karachi was presented before Registration Board.

After Through discussion about (OOS) Investigation report submitted by the firm and deliberation the case in detail and decided

1. not to accede the firm's request for appellate testing of this product and
2. to issue show cause notice under Section 42 of the Drugs Act, 1976 and rules framed thereunder, for suspension / cancellation of product Sterile water for injection (ampoule) Registration # 053244 manufactured by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and called for personal hearing before Registration Board in this instant case.

In view of Board's decision, they were called for personal hearing.

08. Proceedings and Decision of 329th Meeting of Registration Board.

Mr. Muzammil Mehmood Khan, Quality Control Manager of Ms. Mediate Pharmaceutical (Pvt.) Ltd., Karachi was appeared before the Board. He submitted the same stance mentioned in their OOS report.

Board asked about non satisfactory results of OOS performed by firm, self-audit report and water system qualification for which he did not provide any justifiable reply.
Registration Board after thorough discussion and considering the facts of the case along with another similar case of decided:

- *Suspension of the Registration of Sterile Water for injection, Registration No. 053244 under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.*
- *Submission of RCA and CAPA by the firm.*
- *Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*

Panel Inspection Report:

09. Panel conducted the PSI of sterile water for injection 5ml Batch no. W-20017 and W-20024 on 25-10-2023. Panel mentioned in report that they evaluated key documents in detail to determine possible chance of failure or OOS or gaps and during inspection panel also noticed that the firm had kept suspended the manufacturing of WFI as per Registration Board's decision.

- Respective BMR of Batch 0. W-20017 & W-020024 of Water for Injection 5ml.
- Re-Air balancing report of 2nd floor Air Handling Unit (AHU No. 09 & 14) by a third party Technocratics Pvt. Ltd., conducted after failure.
- HEPA Filter Integrity retest Report by Technocratics Pvt. Ltd.,
- Re-validation Report of Passivation Process for WFI Loop System and Storage Tank by Technocratics Pvt. Ltd.,
- Re-validation report of Dry Heat Sterilizers
- Re-validation report of Autoclave
- Revised validation Protocol for Re-Qualification of distilled water plant.
- Revised Validation protocol for Bacterial Endotoxin Test for water for injection readdressed.
- All other relevant record and SOPs for determining the possible chances of contamination into the sterile products.
- Repeat test results including raw data of TOC analyzer, Conductivity & pH meter reports that also included the in-depth review of their BET Kits, methods and preparation and handling of samples, sterility testing SOPs records and equipment's validation and calibration records.
- PC IR lab report of respective batch (copy enclosed).
- Root Cause Analysis (RCA) Reports (Copy enclosed).

10. Firm mentioned in **conclusion of their CAPA** that keeping in view the decision of registration board they had conducted the following **possible root causes** of the problem:

- Review of Respective BMR of Batch NO. W-20017 & W-20024 of Water for Injection 5ml.
- Air balancing report of 2nd floor air handling Unit (AHU No. 09 & 14) by a third party Technocratic Pvt. Ltd.,
- HEPA Filter Integrity Test Report by Technocratic Pvt. Ltd
- Validation Report of Passivation Process for WFI Loop System and Storage Tank by Technocratic Pvt. Ltd.
- Validation report of Dry Heat Sterilizers
- Validation report of Autoclave
- Validation Protocol for Re-Qualification of distilled water plant.
- Validation protocol for Bacterial Endotoxin Test for water for injection.
- All other relevant record and SOP's for determining the possible chances of contamination into the sterile products.
- Repeat test results including raw data of TOC analyzer, Conductivity, Biological and chemical indicators & pH meters' report that also included the in-depth review of their BET Kits, methods and preparation and handling of samples, sterility testing SOPs records and equipment's validation and calibration records.
- PCSIR lab report of respective batches used in Endotoxin test Method validation of sterile water for injection with interval period of one month in manufacturing dates, their reports shows the consistency in Area of manufacturing & Results.

11. **Conclusion of the panel** is mentioned below:

"Keeping in view of above mentioned facts, the panel unanimously recommends that their suspended registration of Water for Injection (Reg. No. 053244) may be resumed with the

condition to retest their first batch of Water for Injection again for better safety and quality of the products manufactured by the firm."

Proceedings and Decision of 336th Meeting of Registration Board.

The Board after considering the facts of the case and after thorough deliberations and keeping in view recommendation of panel of experts in it inspection report dated 25.10.2023 decided:

i. "To resume the production of Sterile Water for injection, Registration No. 053244 of M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi.
ii. Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to the standard report by the Central Drugs Laboratory, Karachi."

Case No. 05: MANUFACTURE & SALE OF SUB-STANDARD LEFIN PEDIATRIC SUSPENSION, REG. NO. 000404, BATCH NO. 332V, MANUFACTURED BY M/S. LEAMA CHEMI PHARMA (PVT) LTD. PESHAWAR.

The Federal Inspector of Drug Peshawar inspected the premises of M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar on 12-08-2021 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Results
Lefin Pediatric Suspension (Paracetamol)	M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar.	000404	332V	06/21	05/23	Sub-Standard on the basis of Assay.

02. Results of CDL on the basis of which samples under reference has been declared as Substandard quality are reproduced as under:-

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Pink coloured suspension in ambered glass bottles.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Paracetamol.	Complies.	BP 2020
4.	**Assay** Paracetamol. (Label Claim 120mg/5ml)	95.0% to 105.0%	**70.45%- Does not comply.**	BP 2020

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

03. FID has sent the explanation letter to explain their position dated 26-10-2021 regarding the violation of Drug Act 1976 and DRAP Act 2012.

04. The firm has submitted their reply dated 29-11-2021, wherein they requesting for retesting of product Lefin Pediatric Suspension Batch no. 332V.

05. The agenda of "Handling requests of Appellate Testing- Guidance document for registration Board" was discussed in 313th meeting of Registration Board. The Board after thorough deliberations and considering the facts of the case decided as:

i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case.

06. The firm's response received dated 14-02-2022. Firm has submitted testing method on UV and it seems that assay method on HPLC was added afterwards as document show did not show serial No. on HPLC method.

07. CDL submitted the response dated 15-03-2021 wherein they mentioned: OOS is validated.

08. Technical Evaluation of the case:

i. The product was declared substandard by CDL on the basis of assay.
ii. CDL performed the test as per BP 2020.
iii. Testing method of firm was not a control document.
iv. HPLC was not standard method, they mentioned UV for assay in testing method.

v. Firm performed assay on HPLC dated 10-12-2021 while the parameters i.e mobile phase, standard preparation, sample preparation, wavelength, flow rate was not as per BP 2020.

Parameters	BP Parameters	CDL parameters	Firm's Parameters
Flow rate	1.5ml/min	1.5ml/min	1ml/min
Column temperature	35	35	-
Detection wavelength	245nm	245nm	256nm
Inject volume	50ul	50ul	10ul

vi. Audit trail was not provided by firm.

vii. Data is not time stamped hence data integrity cannot be verified.

09. Proceedings of 317th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar and CDL, DRAP Karachi was presented before Registration Board. The Board deliberated the case in detail as follows:

i. Registration Board considered the case of M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar requested for Appellate testing. In compliance to the decision of 313th meeting of Registration Board, the firm and CDL were asked to submit Out of specification (OOS) investigation vide office letter dated 23-12-2021. The firm submitted the response dated 14-02-2022. Firm has submitted testing method on UV and it seems that assay method on HPLC was added afterwards as document does not show serial No. on HPLC method. While CDL submitted the response dated 15-03-2022 wherein they mentioned: OOS is validated.

ii. Review of documents revealed that the product "Lefin Pedriatic Suspension" (Reg# 015203) was registered vide letter No.F.3-3/97-Reg.II(M-125) dated27th June 1997 and no specification was mentioned in registration letter. Later on the subject product was included in BP specifications while the firm is still manufacturing and testing the product per manufacturer specifications. Further in 197th meeting of Registration Board held on 3-4th May 2006, the Board decided as:

> "All the firms shall adopt the specifications mentioned in the official pharmacopoeias for all the formulation except those drugs not included in the official pharmacopoeias. For these drugs manufacturers may adopt their own specifications till the inclusion of that formulation in the official pharmacopoeias. after this decision firms will not be allowed to adopt their own specifications for the drugs, which are included in any of the official pharmacopoeias, listed in the Section 3 of Drugs Act, 1976."

10. Decision: Keeping in view position narrated above the Board concluded that the firm is still manufacturing/testing the said product as per manufacturer specifications despite of the fact that it is included in the official pharmacopoeia (BP). Therefore, Board did not accede the firm's request of appellate testing. Thus, the Board decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar and called them for personal hearing before Registration Board.

11. Decision of 317th meeting of Registration Board had been communicated vide letter No. F.03-30/2022-QC (317-RB) dated 21-06-2022.

12. Firm has replied vide Ref. No. Nil dated 30-06-2022 wherein they provided HPLC analysis and requested to accept the same. Firm was called for personal hearing in 320th meeting of Registration Board.

13. Proceedings and Decision of 331st Meeting of Registration Board.

- Mr. Irfan Wahid, QCM (CNIC# 17301-1469985-7) and M. Ibrar Khalid, Production In charge (CNIC# 17301-1666657-5) appeared before the Board. They said that they performed the assay by UV spectroscopy and after the substandard report received they performed the assay by HPLC method.
- "Registration Board after considering the facts of the case and thorough deliberations decided to suspend the registration of the said product for six (06) months or till the verification of root cause analysis, Corrective and preventive action (CAPA) by the firm and verification of aforementioned points and Product Specific Inspection by following panel whichever is later.
  - Director DTL Peshawar.
  - Additional Director, DRAP, Peshawar"

14. FID, Peshawar submitted PSI report vide letter no. F.11-22/2024-Leama-DRAP-137. Inspection was conducted on 20.07.2023 against DRAP letter for verification of CAPA of substandard Lefin suspension Batch no. 332V, however the firm was given further recommendations to implement CAPA in

letter in spirit. The firm's management requested for some time and panel agreed for 3-month time for implementing of CAPA.

15. Panel checked and evaluated following parameters:

S.No.	Panel Questions	Firm's Reply	Panel Views/ Comments
1.	Did the firm identified quality risks associated their product for sub-standard results or Root cause Analysis was performed?	The firm's technical persons stated that one of the problem is frequent change of vendors resulting in stability issued of the product. The firm has devised vendor qualification SOP (Annex-VI) and fixed new source of API as Citi Pharmaceuticals Lahore.	Root cause is identified by the firm and necessary SOP has been devised/ implemented for the fixing source of API followed by further proceedings as per product development on new source of API. Three trial batches B. 001, 002 and 003 are placed on stability studies.
2.	Did the firm has vendor qualification procedure?	SOP is devised/ implemented.	Since the RC was identified as non-qualification of vendor, the firm has now implemented the SOP for source fixation of Paracetamol API. The firm has fixed the source of API as Citi Pharma, Lahore
3.	How CAPA was prepared?	New vendor API is used for the product and results were in compliance. The firm also informed that they have used official testing method now and results of product are in compliance.	CAPA was implemented with new formulation development limited to trial batches. The firm plan to resume commercial batches after permission from DRAP and has agreed/ committed for conducting stability studies on commercial batches as and when manufactured. The official testing method (BP 2023) for product is also adopted by the firm.
4.	Any change in the formulation has taken place?	The firm informed that they have changed the formulation.	The has also changed the formulation having following amendments (Addition of Sorbitol 70%). The trial batch reports indicate analytical results in limit. The is also advised to ensure testing of Sorbitol excipient for EG/ DEG in solvents or get sample tested from authorized labs to ensure their safety.
5.	If formulation is changed, stability study was conducted and what was stability testing protocol?	Three trial batches has been manufactured by the firm and placed on stability studies. Testing data indicated the product is stable.	The firm has adopted pharmacopeial testing method (B.P 2023) and followed all the steps provided in their SOP for new testing method. The firm is also directed to ensure testing of impurities EG/DEG in solvents or get sample tested from authorized labs to ensure their safety.
6.	The firm was asked to present any other	The firm has provided following documents. 1. Vendor Qualification.	Scientific data/ product testing record has neem provided by the

	relevant documents for evaluation.	2. Trial batches stabilities 3. Product development 4. Root cause analysis 5. Change control	firm to accept the CAPA plan of the firm.

16. In conclusion, the panel was of the view that the firm has taken necessary steps for CAPA implementation. The management of the firm had given commitment to conduct stability studies on commercial batches as and when allowed by DRAP for commercial scale production. Further, the firm was also directed to adopt proper change control, risk evaluation of all the changes to be implemented and review of their CAPA to ensure its effectiveness.

17. **The panel recommended resumption of production of Lefin pediatric suspension with condition of adoption of change control, risk evaluation, CAPA review and all the further steps to ensure the quality of their product.**

Proceedings and Decision of 336th Meeting of Registration Board.

The Board after considering the facts of the case, keeping in view recommendations of panel of experts in its report dated 20.07.2023 and after thorough deliberations decided:

i. "To resume the production of Lefin Pedriatic Suspension, Registration No. 015203 of M/s. Leama Chemi Pharma (Pvt) Ltd. Peshawar.
ii. Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to the standard report by the Central Drugs Laboratory, Karachi."

Case No. 06: SUBSTANDARD ESPEZAR CAPSULE MFG. BY AVANT PHARMACEUTICALS (PVT.) LTD., HUB, BALOCHISTAN.

01. Federal Government Analyst, CDL Karachi vide test report No. KQ-10-23000127 declared the batch A401 of product Espezar Tablet manufactured by M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub, as of substandard quality. Details of CDL test report are as under:

S.No.	Product	Mfg. by	Batch No.	CDL Test Result
01	Espezar Tablets	M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub Balochistan.	A401	Dissolution (Acid stage) **Does not comply** Assay 84.96% **Does not comply**

02. Firm was ordered to recall the defected batch of the product in question and Federal Inspector of Drugs-II Karachi was directed to investigate the matter and submit a comprehensive report in the matter. FID-II Karachi vide letter F. ARS-112-113/2023-FID-lI (K) dated 27-12-2023 submitted show-cause letter issued to firm by FID II Karachi, BMR of batch A401 of product Espezar Tablet and request of firm for appellate testing of their product under Section 22(4) of the Drugs Act, 1976.

03. Registration Board in its 313th decided as under:

"Proceedings and Decision of 313th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided as:
i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."

04. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. No. 03-46/2023-QC requested the Federal Government Analyst CDL Karachi and M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub for the submission of OOS investigation as directed by the Board.

05. Summary of OOS investigation is given as under:

Summary of OOS investigation submitted by M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub.

M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub Balochistan in their reply has provided OOS investigation report wherein they have ruled out any chance of error in the testing of their product. Along with the said reply, the firm has annexed "Certificate of Analysis" and HPLC chromatograms of their retention sample and have concluded that no error was found in testing and the product complies with the innovator's specification.

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi.

Federal Government Analyst, CDL Karachi has also submitted that they have tested the product as per innovator's specifications and has provided detailed method for test/analysis. Moreover, in the provided OOS investigation report, FGA CDL Karachi has ruled out any possibility of error in the test/analysis method.

06. Proceedings and Decision of 336th Meeting of Registration Board.

Out of Specification (OOS) investigation provided by the firm and by Federal Government Analyst, CDL Karachi were presented before Registration Board. The Board deliberated on the OOS investigation and did not agreed with the OOS investigations submitted by the firm. The Board did not accede to request of the firm for appellate testing and decided to issue show cause notice to M/s. Avant Pharmaceuticals (Pvt.) Ltd., Hub Balochistan under Section 42 of the Drugs Act, 1976 and called them for personal hearing before Registration Board in its forthcoming meeting.

Meeting ended with a vote of thanks to and from the Chair

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